



IMPACT:

“Acquis communautaire” audits

Checklist – Products covered by the New Approach directives

Sofia, 19-20 June 2008

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Checklist New approach directives

Overview of presentation

1. Overview total checklist
2. Background for understanding part 2: EU directives for products covered by the new approach
 1. Clarification of the concept of CE marking
 2. Backgrounds on CE marking
 3. Acquisition of CE marking (conformity assessment)
3. Overview different directives: general background for auditing



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Checklist New approach directives

1. Overview total checklist

I. General positioning and awareness of the standardization

- I.1 Identification of the company*
- I.2 Responsibilities in placing CE marked products on the market*
- I.3 Awareness of EU legislation*



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Checklist New approach directives

1. Overview total checklist

II. EU directives for products covered by the new approach, requiring CE-marking

- II.1 Toys*
- II.2 Machines*
- II.3 Pressure equipment*
- II.4 Medical devices*
- II.5 Electrical and electronic equipment and gas appliances*
- II.6 Radio and telecommunications terminal equipment*



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Checklist New approach directives

1. Overview total checklist

II. EU directives for products covered by the new approach, requiring CE-marking

- I.7 Boats: recreational craft*
- II.8 Metrology*
- II.9 Explosives intended for civilian use*
- II.10 Materials used outdoors*
- II.11 Construction products*
- II.12 Personal protective equipment*
- II.13 Equipment and protective systems intended for use in potentially explosive atmospheres*



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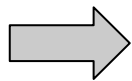


Checklist New approach directives

2.1 Clarification of the concept CE marking

CE MARKING (Decision 93/465/EEC, Directive 93/68/EEC)

- Indication that the **product harmonizes/conforms** with the levels of safety and protection, indicated by the European directives
- Indication that the product has followed the **conformity assessment procedures**, indicated by the European directives



CE marking comprises more than just satisfying the rules of safety!



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Checklist New approach directives

2.1 Clarification of the concept CE marking

- **Directive** = regulation approved by European Commission and which should be transferred into national regulation
- **Conformity assessment procedure** = procedure in which systematically is described to which extent a product, process or service applies to the directives' and/or standards' requirements
- **Notified body** = organisation authorized+competent to complete certain tasks as described in the directives

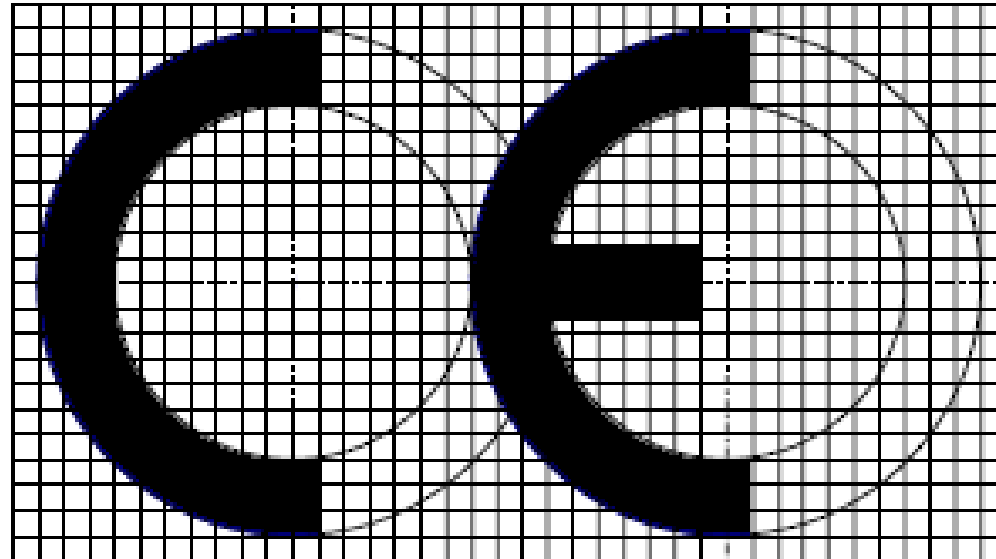


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Checklist New approach directives

2.1 Clarification of the concept CE marking



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Checklist New approach directives

2.1 Clarification of the concept CE marking

- *Is the application of CE marking a guarantee of safety?*
 - ➔ in principle CE marked products are safe products, but there is never an absolute guarantee of safety
- *Is the application of CE marking a guarantee of inspection by a registered organisation?*
 - ➔ not necessarily!



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Checklist New approach directives

2.2 Backgrounds on CE marking

- *Why introducing CE marking?*
- *Basis of European instructions?*
 - Essential requirements = basis for being authorized to enter a member state
 - Essential requirements = basis of instructions laid on the design, production, importation and sales of the product, for reasons of risk minimization
 - Harmonization of the specific, national rules and laws



essential requirements vs. the harmonized standards



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Checklist New approach directives

2.2 Backgrounds on CE marking

- *European directives*
 - Made up **per product group**
 - Determine the **general fundamental requirements (technical specifications)**
 - **Completed** by adding the **harmonized standards**, giving more details (CENELEC, CEN)

Conformity with harmonized standards or fundamental requirements with CE marking



- presumption of **conformity**
- 'entrance card' to **circulating freely** on the European market



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Checklist New approach directives

2.2 Backgrounds on CE marking

CE marking

= harmonized methods for assessing conformity with the technical harmonisation directives:

- promote the placing on the market of industrial products
- assist in implementation of the internal market

Council Decision 93/465/EEC

This Decision lays down general guidelines and detailed procedures for conformity assessment that are to be used in *New Approach directives*.



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Checklist New approach directives

2.2 Backgrounds on CE marking

3 fundamental pillars

1. Council Resolution of 07.05.1985, where a 'New Approach to technical harmonization and standards' is seen as an essential condition for improving the competitiveness of European industry.
2. Council Resolution of 21.12.1989 on a Global Approach to certification and testing, which states the guiding principles for Community policy on conformity assessment.
3. The Global Approach was completed by Council Decision 93/465/EEC. This Decision lays down general guidelines and detailed procedures for conformity assessment that are to be used in New Approach directives.



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Checklist New approach directives

2.2 Backgrounds on CE marking

Technical harmonization

= *acknowledgement between different member states of results of approvals and examinations*

If the product is approved within one state, it is automatically approved in
→ other states as well

Main goals of the 'New Approach':

- Free movement of goods within EU
- Acceleration of harmonization concerning safety and health requirements

Other positive influences (compatibility, safety of employees, improvement of consumers' safety, ...)



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Checklist New approach directives

2.3 Acquisition of CE marking

Two possibilities:

- Following harmonized standards
 - *Proven by a technical file*
 - *Presumption of conformity*
 - Application of CE marking by MF

- Following essential requirements
 - Approval by recognized organisation

- Variations on the above, depending on directive applicable



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Checklist New approach directives

2.3 Acquisition of CE marking

Steps in CE marking

- ✓ *Research/ information gathering*
- ✓ *Which directive(s) is (are) applicable?*
⇒ Definitions and exceptions!!! (see directives)
- ✓ *Who is responsible for carrying out the formalities?*



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Checklist New approach directives

2.3 Acquisition of CE marking

Steps in CE marking

✓ *Does your product satisfy the fundamental requirements?*

=> risk analysis

=> if not:

- amendment of the design
- constructive measures (f.ex. protection)
- subscribe personal measures of protection
- warnings on product or manual

(harmonised standards on risk analysis: EN 292-1 and 292-2, EN 414 and EN 1050)



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Checklist New approach directives

2.3 Acquisition of CE marking

Steps in CE marking

✓ *Do you make use of the harmonised standards?*

- possibility to use harmonised standards to *make sure* you satisfy the fundamental requirements
- harmonised *European* standards vs. national standards
- references, see European Publication
- if yes, note in the EG declaration of conformity and technical file
- for specific products or product groups, goes into detail



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Checklist New approach directives

2.3 Acquisition of CE marking

Steps in CE marking

✓ *Is the approval of a notified body necessary?*

- dependant on directives' requirements
- if yes, fundamental requirements must be checked by notified body
- does not necessarily need to be a body of own country
- approved bodies are prescribed in applicable directives' references
- depending on risk in using the product



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Checklist New approach directives

2.3 Acquisition of CE marking

Steps in CE marking

✓ *Make up of a product manual*

- Which precautionary measures should be taken when using the product?
- Language of the user
- Further details, see directives New Approach
- Check by notified body depends on product (-group)



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Checklist New approach directives

2.3 Acquisition of CE marking

Steps in CE marking

✓ *EG declaration of conformity*

- Make up by MF and sign off
- Delivery with each product in language of country of destination
- Content of declaration, see annex of directive
- !!!! For some directives, there are different types of declarations, dependant on whether product is f.ex. a safety component, a final product, a component,...



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Checklist New approach directives

2.3 Acquisition of CE marking

Steps in CE marking

✓ *Technical file*

- All information regarding product and measures for satisfying the fundamental requirements of the directives
- Which procedures are followed for the minimization of risks?
- Design, drawings (technical), test reports, certificates, manuals, ...
- In general, documentation should be kept at disposal at least 10 years after product has been launched onto the market



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Checklist New approach directives

2.3 Acquisition of CE marking

Steps in CE marking

✓ *Application of CE marking*

- !!! Not on all products, covered by new approach directives, CE marking can be applied!
(see directives)
- On some products, other information should be applied
- If notified body involved:
 - Identification number should be added to CE marking, in most cases
 - Year of application of CE marking



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Checklist New approach directives

2.3 Acquisition of CE marking

Steps in CE marking

✓ *Amendment and new developments*

=> 'New' risks in using the product?

- If yes, recapitulation of the procedure is necessary!
- Note well, recapitulate the changes into the technical dossier as well!



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Checklist New approach directives

2.3 Acquisition of CE marking

Steps in CE marking

Conformity assessment procedure:

- Two phases:
 - Approval of the design of the product
 - Confirmation that the final product conforms to this approved design
- Per type of product and related risk the directives prescribe procedures to follow
- Quality systems vs. other procedures



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Checklist New approach directives

2.3 Acquisition of CE marking

Steps in CE marking

- Subdivision into *modules*, which comprise a limited number of different procedures applicable
- In general, product is subject to *conformity assessment during design and production phase*
- Certain *combinations of modules* to be applied
- Each New Approach directive describes:
 - *range and contents* of possible conformity assessment procedures
 - *criteria* governing the conditions under which the manufacturer can **make a choice, if options are provided for**

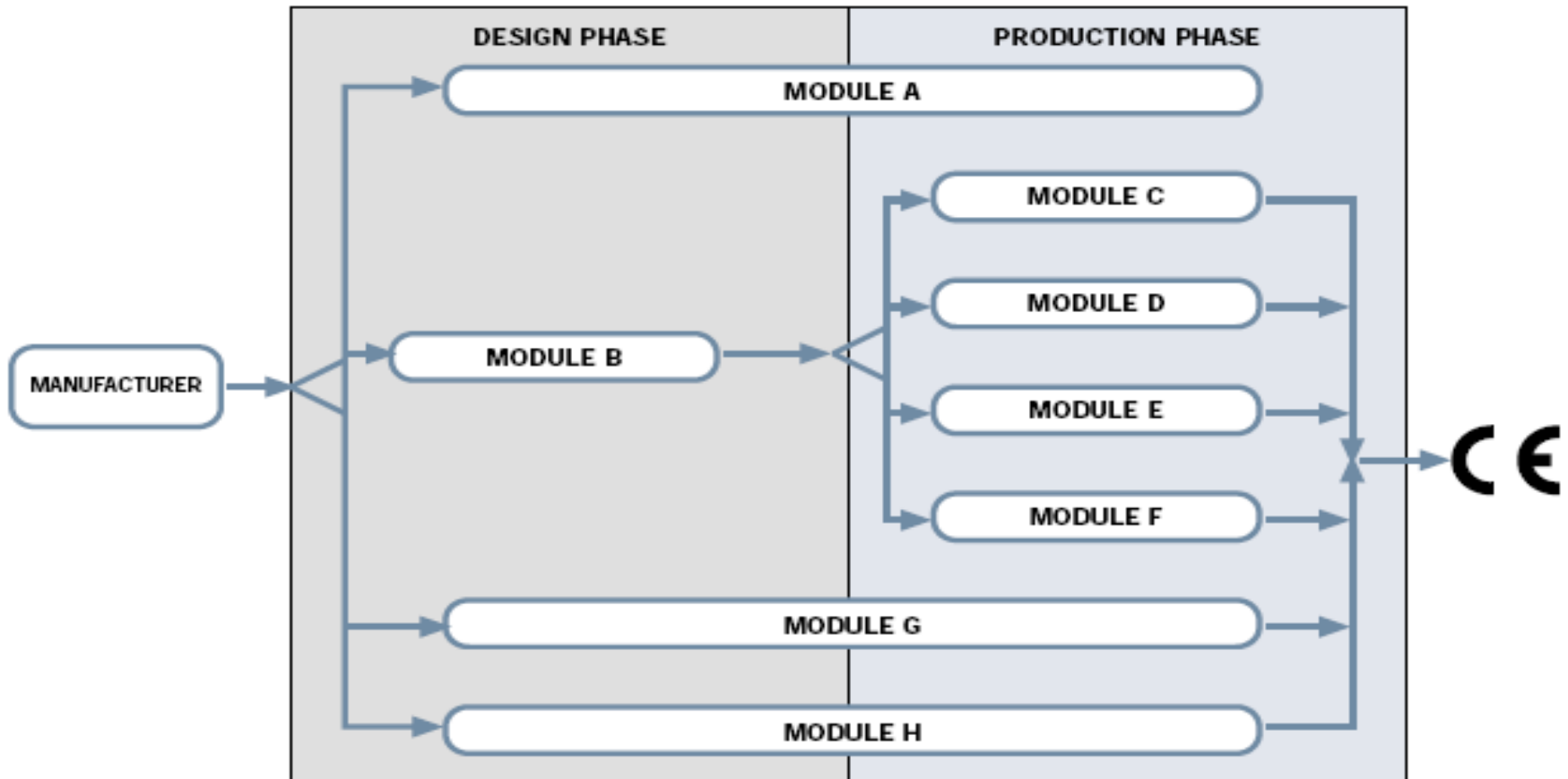


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Checklist New approach directives

2.3 Acquisition of CE marking

Steps in CE marking



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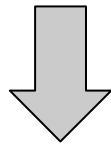
Checklist New approach directives

2.3 Acquisition of CE marking

Steps in CE marking

■ **Module A**

- = internal control of production



- Covers internal design and production control. This module does **not require a notified body** to take action
- Manufacturer makes up a **technical file**, which proves that the product is conform to the directive's fundamental requirements
- Manufacturer makes up a **declaration of conformity** and applies CE marking



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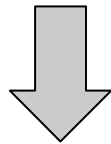
Checklist New approach directives

2.3 Acquisition of CE marking

Steps in CE marking

■ **Module B**

- = EC-type examination



- Covers the design phase, and must be followed up by a module providing for assessment in the production phase. The **EC type-examination certificate** is issued by a **notified body**
- Manufacturer makes up a **technical dossier**, which is the basis of the examination
- This module is obligated **to be followed by**

module(s) **C, D, E or F**



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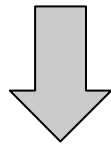
Checklist New approach directives

2.3 Acquisition of CE marking

Steps in CE marking

■ **Module C**

- = Conformity to type



- Covers the production phase and follows module B.
- Provides for as described in the EC type-examination certificate **conformity with the type** issued according to module B.
- **Manufacturer declares** and guarantees that the products examined are conforming to the approved type in module B.
- This module does **not require a notified body** to take **action**.



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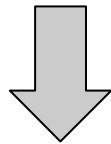
Checklist New approach directives

2.3 Acquisition of CE marking

Steps in CE marking

■ **Module D**

- = Production quality assurance



- Covers the production phase and follows module B
- Manufacturer **declares** that his products are conforming to the approved type (module B) and makes use of a **production quality system** and inspects the final product
- Derives from quality assurance standard **EN ISO 2002**, with the **intervention of a notified body** responsible for approving and controlling the quality system for production, **final inspection and testing, set up by manufacturer**



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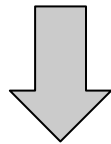
Checklist New approach directives

2.3 Acquisition of CE marking

Steps in CE marking

■ **Module E**

- = Product quality assurance



- Covers the production phase and follows module B
- Manufacturer **declares** that the product is conform to the approved type (module B)
- Manufacturer makes use of a **quality system** and inspects the final product
- Derives from quality assurance standard **EN ISO 2003**, with the **intervention of a notified body** responsible for approving and controlling the quality system for final product inspection and testing, set up by the manufacturer



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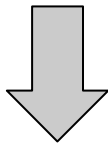
Checklist New approach directives

2.3 Acquisition of CE marking

Steps in CE marking

■ **Module F**

- = Product verification



- Covers the production phase and follows module B
- Manufacturer declares the product is conform to the approved type in module B
- **A notified body controls conformity to the type as described in the EC type-examination certificate issued according to module B, and issues a certificate of conformity**



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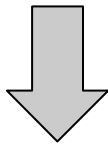
Checklist New approach directives

2.3 Acquisition of CE marking

Steps in CE marking

- **Module G**

- = Unit verification



- Covers two phases: the design and production phases
- **Each individual product is examined by a notified body,** which issues a certificate of conformity



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Checklist New approach directives

2.3 Acquisition of CE marking

Steps in CE marking

■ **Module H**

- Full quality assurance



- Covers **two phases**: the design and production phase
- Manufacturer declares the products to be conform to the directive and makes use of an **approved quality system** for both design, production, control and inspection of final product
- Derives from quality assurance standard EN ISO 9001, with the **intervention of a notified body** responsible for approving and controlling the quality system for design, manufacture, final product inspection and testing set up by **the manufacturer**.



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Checklist New approach directives

2.3 Acquisition of CE marking

Steps in CE marking

Additional elements, compared to the basic modules

=> **See annex 7 of the 'Blue Guide'** , Guide to the implementation of directives based on the New Approach and Global Approach



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Checklist New approach directives

2.3 Acquisition of CE marking

Steps in CE marking

SUMMARY of the general possibilities:

1. Declaration of conformity by manufacturer ('self-certification'): **module A**
2. Product certification: **modules B+C, B+F and G**
3. Product certification with implementation of a quality control system: **modules B+D and B+E**
4. Total quality control and product analysis: **module H**



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Checklist New approach directives

2.3 Acquisition of CE marking

Steps in CE marking

GENERAL RULES:

- If measures on conformity assessment

➔ Declaration of conformity obligated before CE marking is applied!

- If certification is obligated

➔ Intervention of notified body before CE marking is applied

- **If no certification is mentioned in the directive**

➔ CE marking can be applied by manufacturer if accompanied by declaration of conformity



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Checklist New approach directives

2.3 Acquisition of CE marking

Steps in CE marking

SUMMARY of declarations of conformity:

1. Certificates of declaration, by third party
2. Results of an examination executed by third party
3. Declaration of conformity, given out by manufacturer or its importer in the European Union
4. Other declarations (see directives, applying to product)



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Checklist New approach directives

2.3 Acquisition of CE marking

Steps in CE marking

Technical dossier:

- Key element for conformity assessment procedure in
 - Toys
 - Electromagnetic compatibility
 - Machines
 - Personal protective equipment
 - Medical devices
- Consists of two parts:
 - List of essential data (name, address of manufacturer, name product, description, ...)
 - Technical dossier with all the informations on quality control system, plans, descriptions of products and processes, ...



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Checklist New approach directives

2.3 Acquisition of CE marking

Steps in CE marking

- *What if a product does not seem to be worth to be approved, after all?*
 - notified body is responsible for failures in conformity assessment procedure
 - manufacturer is responsible for the product itself !!!

- *What and who are notified bodies?*

=Inspection bodies/organisations who are found to be:

 - technical competent
 - objective
 - transparent
 - Answer to the reglementary binding criteria, as set out by the directive
 - Assessed by the Member states, i.e. they are responsible for their notification
 - Use of standards, relevant for notified bodies



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Checklist New approach directives

2. Background for understanding part 2

Questions on general part?



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Checklist New approach directives

I. General positioning and awareness of the standardization

I.1 Identification of the company

I.1.1 Company's activities on EU-market

I.1.2 Conformity Assessment

I.1.2.1 Quality awareness in the production process

I.1.2.2 Testing procedures

I.1.2.3 Certification process



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Checklist New approach directives

I. General positioning and awareness of the standardization

I.2 Responsibilities in placing CE marked products on the market

I.2.1 Essential requirements

I.2.1.1 General product safety

I.2.1.2 General product liability



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Checklist New approach directives

I. General positioning and awareness of the standardization

1.3 Awareness of EU legislation

1.3.1 Scope of EU legislation

1.3.2 Coverage by New Approach legislation



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Checklist New approach directives

II. EU directives for products covered by the new approach, requiring CE-marking

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Checklist New approach directives

II. EU directives for products covered by the new approach

- I.7 Boats: recreational craft*
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Checklist New approach directives

II.1 Toys

II.1. Toys *Directive 88/378/EC*

II.1.2 *Toys that use percussion caps*
maximum sound pressure level of 124 dB!!!
(Commission Decision 2001/579/EC)

II.1.3 *Phthalate-containing soft PVC toys and childcare articles*
toys intended to be placed in the mouth by children under 3 years of age ?

=> prohibition of the use of phthalates in children's toys!!!
(Dir. 2001/95/EEC, amended by Dir. 2005/84/EC)



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Checklist New approach directives

II.1 Toys

= any product or material designed or clearly intended for use in play by children of less than 14 years of age

Annex I : products not regarded as toys for the purpose of this directive

Examples of exclusions:

Christmas decorations, sports equipment, puzzles with more than 500 pieces, slings and catapults, air guns and air pistols, ...



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Checklist New approach directives

II.1 Toys

Harmonisation of fundamental requirements

Annex II: fundamental safety requirements for toys

In compliance with the requirements of Article 2 of the Directive, the users of toys as well as third parties must be protected against health hazards and risk of physical injury when toys are used as intended or in a foreseeable way, bearing in mind the normal behaviour of children



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Checklist New approach directives

II.1 Toys

- *Annex II: fundamental safety requirements for toys*
 - *Particular risks:*
 - *Physical and mechanical properties*
 - *Flammability*
 - *Chemical properties*
 - *Electrical properties*
 - *Hygiene*
 - *Radioactivity*

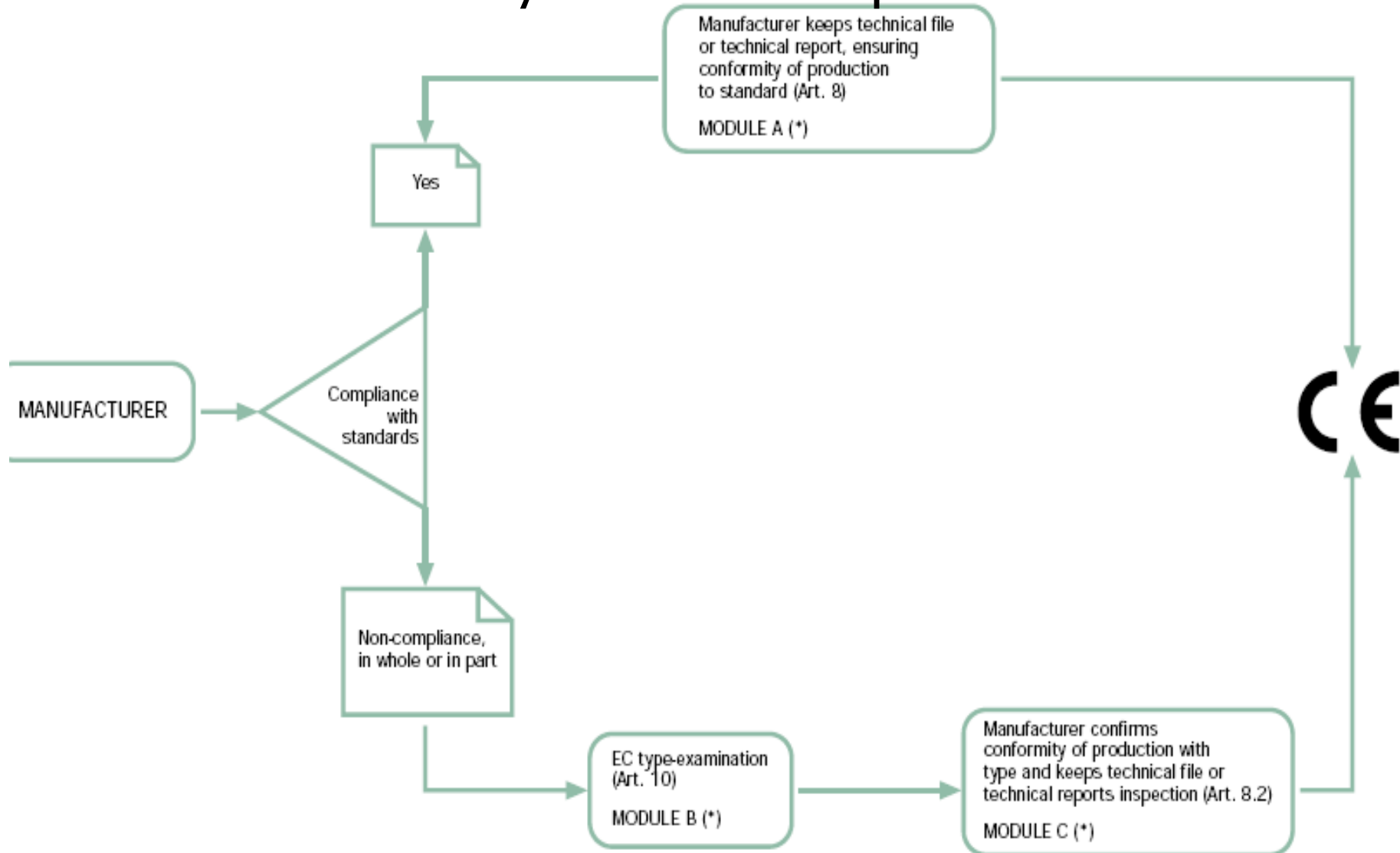


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TOYS - Directive 88/378/EEC

Conformity assessment procedure





Checklist New approach directives

II. EU directives for products covered by the new approach

II.2. Machines

II.2.1 Identification of the product

I.2.1.1 Hoisting and lifting tools

II.2.1.2 Movable and interconnected parts, products for specific uses

II.2.1.3 Combination of machines

II.2.1.4 Changeable part

II.2.1.5 Safety component

II.2.1.6 Human physical energy as a source of power

II.2.1.7 Other categories



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Checklist New approach directives

II. EU directives for products covered by the new approach

II.2. Machines

Directive 98/37/EC

II.2.2 Machines: general

II.2.2.1 Requirements regarding health and safety

II.2.2.2 Requirements regarding conformity assessment

II.2.2.3 Harmonized standards



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Checklist New approach directives

II.2 Machines

- Application to ‘machinery’ and ‘safety components’ when they are placed on the market separately

- Machinery
 - an assembly of linked parts or components, at least one of which moves, with the appropriate actuators, control and power circuits, etc., joined together for a specific application, in particular for the processing, treatment, moving or packaging of a material
 - an assembly of machines which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole
 - interchangeable equipment modifying the function of a machine, which is placed on the market for the purpose of being assembled with a machine or a series of different machines or with a tractor by the operator himself in so far as this equipment is not a spare part or a tool



Checklist New approach directives

II.2 Machines

- Application to ‘machinery’ and ‘safety components’ when they are placed on the market separately
- Safety components
= component, provided that is not interchangeable equipment, which the manufacturer or his authorised representative established in the Community places on the market to fulfil a safety function when in use and the failure or malfunctioning of which endangers the safety or health of exposed persons

Examples:

machinery used in the process for manufacturing products, vehicles used in the mining industry, particularly hazardous machinery (see annex IV), presses, plastic injection machinery with manual loading or unloading, ...





Checklist New approach directives

II.2 Machines

Annex I: essential health and safety requirements relating to the design and construction of machinery and safety components

1. *Essential health and safety requirements*
2. *... for certain categories of machinery*
3. *... to offset the particular hazards due to the mobility of machinery*
4. *... to offset the particular hazards due to a lifting operation*
5. *... for machinery intended for underground work*
6. *... to offset the particular hazards due to the lifting or moving of persons*



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Checklist New approach directives

II.2 Machines

Annex II:

- A. Contents of the **EC declaration of conformity for machinery***
- B. Contents of the **declaration by the manufacturer** or his authorised representatives established in the Community (Article 4(2))*
- C. Contents of the **EC declaration of conformity for safety components** placed on the market separately*

Annex VI:

*types of machinery and safety components for which **the more complex procedure** (see art. 8(2)(b) and (c)) must be applied
=> EC type examination*



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Checklist New approach directives

II.2 Machines

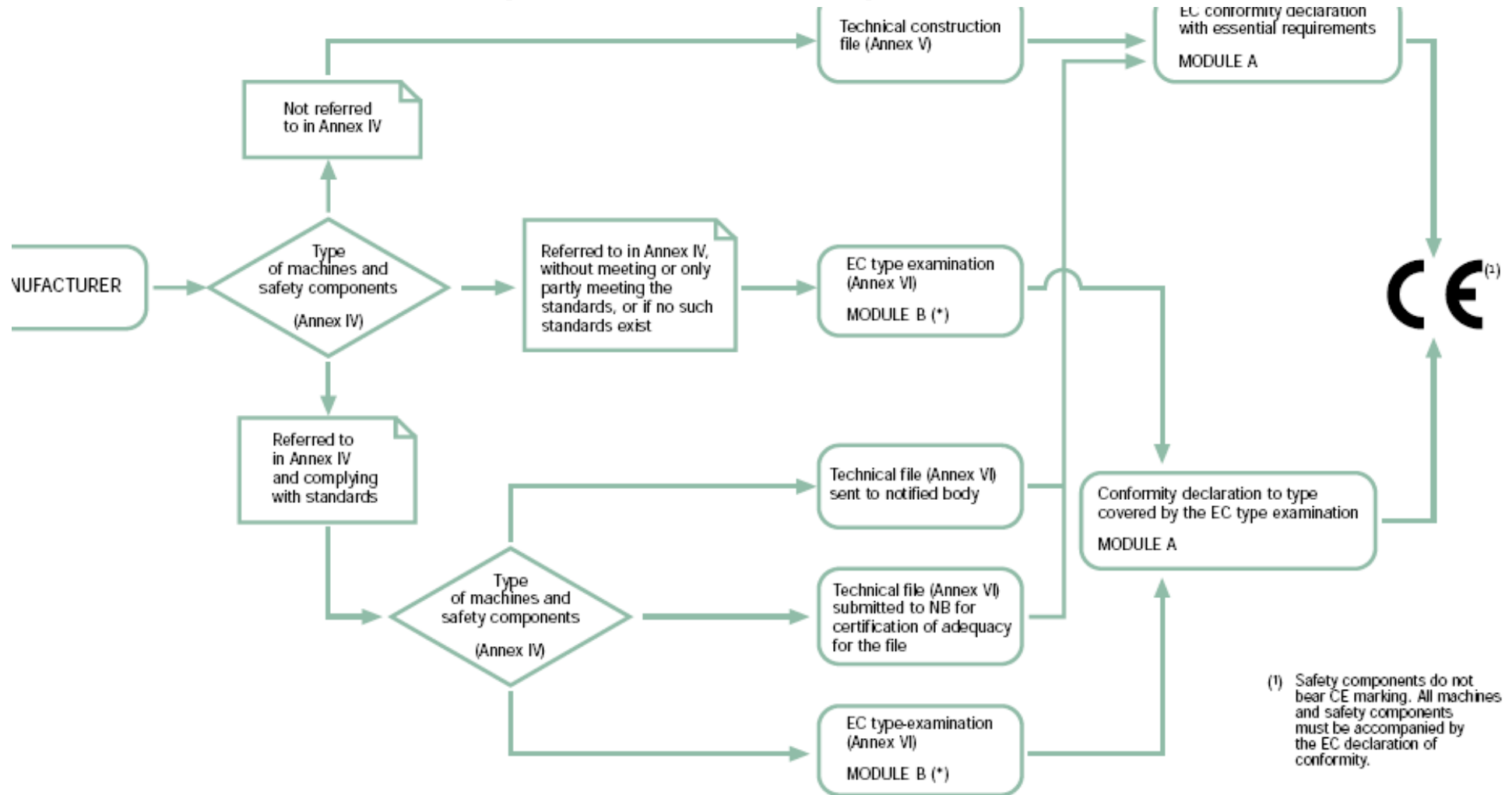
- *Directive 2006/42/EC was published on 9th June 2006.*
- It came into force 20 days later on 29th June 2006. The Member States have until 29th June 2008 to adopt and publish the national laws and regulations transposing the provisions of the new Directive into national law.
- The provisions of the new Directive become applicable on 29th December 2009. Until that date, the provisions of the current Machinery Directive 98/37/EC continue to apply.



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Machines – Directive 98/37/EC

Conformity assessment procedure



(1) Safety components do not bear CE marking. All machines and safety components must be accompanied by the EC declaration of conformity.





Checklist New approach directives

II. EU directives for products covered by the new approach, requiring CE-marking

II.2. Machines

II.2.3. Cableways for the carriage of passengers Directive 2000/9/EC

II.2.3.1 Requirements regarding inspection and assembly procedures

II.2.3.2 Requirements regarding conformity assessment

II.2.3.3 Harmonized standards



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Checklist New approach directives

II.2 Machines - Cableways for the carriage of passengers

= installations made up of several components, designed, manufactured, assembled and put into service with the object of carrying persons. These on-site installations are used for the carriage of persons in vehicles or by towing devices, whereby the suspension and/or traction is provided by cables positioned along the line of travel



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Checklist New approach directives

II.2 Machines

= installations concerned are:

- (a) funicular railways and other installations with vehicles mounted on wheels or on other suspension devices where traction is provided by one or more cables;
- (b) cable cars where the cabins are lifted and/or displaced by one or more carrier cables; this category also includes gondolas and chair lifts;
- (c) drag lifts, where users with appropriate equipment are dragged by means of a cable.



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Checklist New approach directives

II.2 Machines

Annex II: essential requirements

- maintainability and operability, applicable to the design, construction and entry into service of installations
- general requirements
- infrastructural requirements
- requirements regarding cables, drives, brakes and to electrical and mechanical installations
- ...

Annex III: safety analysis

***=> safety report must be made up after
conduction of a risk analysis***



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Checklist New approach directives

II.2 Machines

Annex IV: EC declaration of conformity for safety components

Annex VI: EC declaration of conformity for subsystems (s.a. electrotechnical devices, cables, brakes, ...)



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Cableways for the carriage of passengers – Directive 2000/9/EC Conformity assessment procedure

Summary of possibilities:

Module B + D

Module B + F

Module G

Module H



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Checklist New approach directives

II. EU directives for products covered by the new approach

II.2. Machines

II.2.4. Lifts Directive 95/16/EC

- II.2.4.1 Requirements regarding safety*
- II.2.4.2 Requirements regarding conformity assessment*
- II.2.4.3 Harmonized standards*
- II.2.4.4 Involvement of a notified body*



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Checklist New approach directives

II.2 Machines - Lifts

= appliance serving specific levels, having a 'car' moving along guides which are rigid and inclined at an angle of more than 15 degrees to the horizontal and intended for the transport of:

- persons*
- persons and goods*
- goods alone if the car is accessible, that is to say, a person may enter it without difficulty, and fitted with controls situated inside the car or within reach of a person inside*

Exclusions such as: mining lifts, lifts at construction sites, lifts that are part of a vehicle, ...



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Checklist New approach directives

II.2 Lifts

Annex I: essential health and safety requirements relating to the design and construction of lifts and safety components

- 1. General requirements*
- 2. Hazards to persons outside the car*
- 3. Hazards to persons in the car*
- 4. Other hazards*
- 5. Marking*
- 6. Instructions for use*

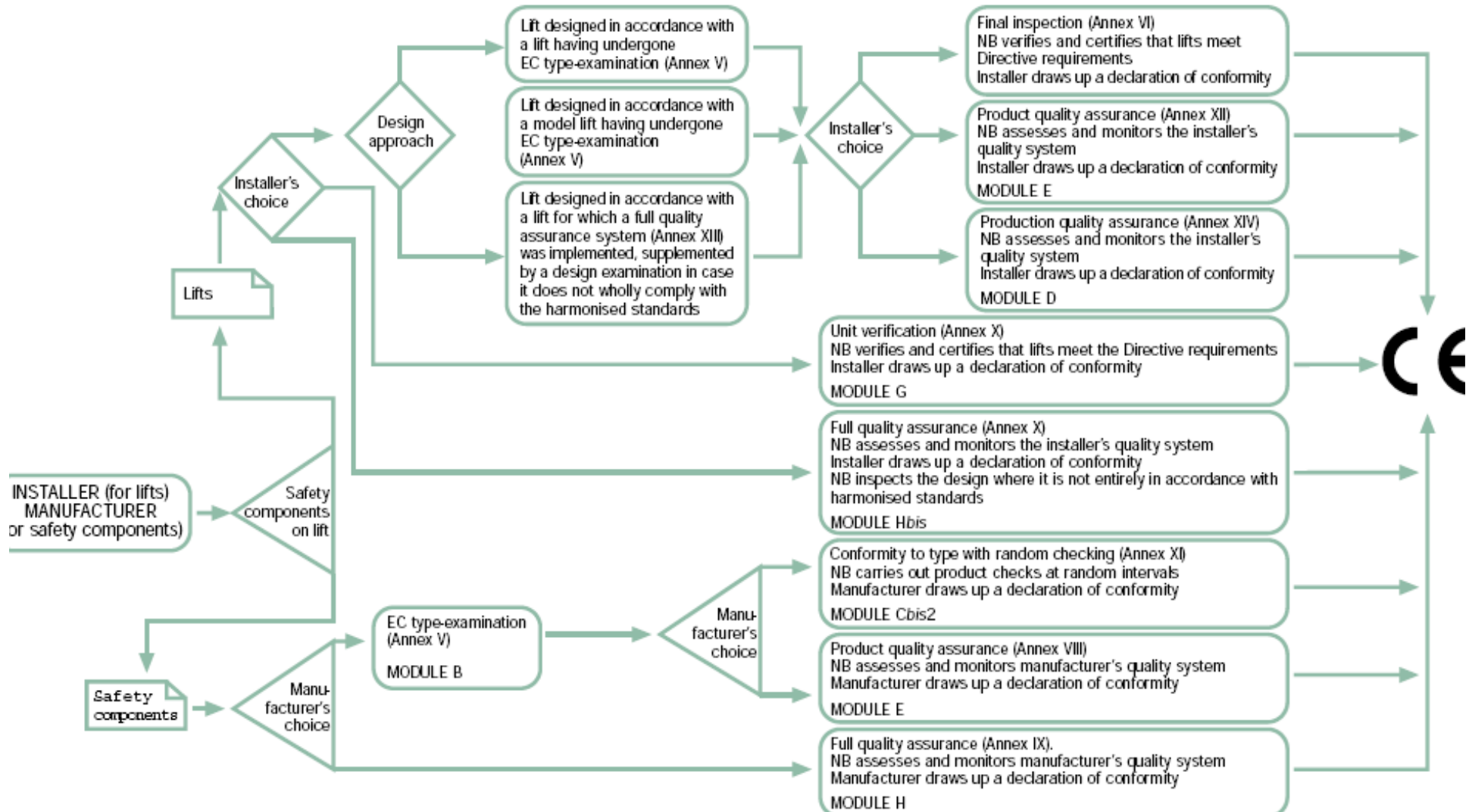


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Lifts – Directive 95/16/EC

Conformity assessment procedure





Checklist New approach directives

II. EU directives for products covered by the new approach

II.3. Pressure equipment

II.3.1 Pressure equipment: general Directive 97/23/EC

II.3.1.1 Requirements regarding safety

II.3.1.2 Requirements regarding conformity assessment

II.3.1.3 Harmonized standards



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Checklist New approach directives

II.3 Pressure equipment

= *Design, manufacture and conformity assessment of pressure equipment and assemblies with a maximum allowable pressure PS > 0,5 bar*

= *vessels, piping, safety accessories and pressure accessories*

= *where applicable, pressure equipment includes elements attached to pressurized parts, such as supports, lifting lugs, nozzles, couplings, ...*

Exclusions such as: *piping, distribution and discharge of water, appliances and machines covered by other directives (see art. 1)*



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Checklist New approach directives

II. EU directives for products covered by the new approach

II.3. Pressure equipment

II.3.2 Use of dangerous fluids in pressure equipment

=> 2 groups of fluids: non-dangerous and dangerous



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Checklist New approach directives

II.3 Pressure equipment

Fluid to be contained is divided into:

Group 1 (DANGEROUS) comprises fluids defined as:

- explosive,
- extremely flammable,
- highly flammable,
- flammable (where the maximum allowable temperature is above flashpoint),
- very toxic,
- toxic,
- oxidizing

■ Group 2 (NOT DANGEROUS) concerns: other fluids (art. 9)



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Checklist New approach directives

II.3 Pressure equipment

- Annex I: essential safety requirements*
- 1. General*
 - 2. Design*
 - 3. Manufacturing*
 - 4. Materials*
 - 5. Fired or otherwise heated pressure equipment with a risk of overheating*
 - 6. Piping*
 - 7. Specific quantitative requirements*
- Annex II: conformity assessment tables => defines categories I to IV*
- Annex III: conformity assessment procedures*



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Checklist New approach directives

II. EU directives for products covered by the new approach

II.3. Pressure equipment

II.3.3 Transportable pressure equipment

II.3.3.1 Requirements regarding safety

II.3.3.2 Requirements regarding conformity assessment

II.3.3.3 Harmonized standards



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Checklist New approach directives

II.3 Pressure equipment – transportable P.E.

= transportable pressure equipment approved for inland transport of dangerous goods by road and rail

Specifically:

- all receptacles (such as cylinders, tubes, pressure drums)*
- all tanks, incl. demountable tanks, tank containers (mobile tanks), tanks or receptacles of battery vehicles or battery wagons, ...*



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Checklist New approach directives

II. EU directives for products covered by the new approach

II.3. Pressure equipment

II.3.4 Transport of goods by road and/or rail

II.3.4.1 Minimum examination requirements for safety advisers

II.3.4.2 Requirements regarding conformity assessment

II.3.4.3 Harmonized standards

II.3.4.4 Minimum appointment and vocational qualification of safety advisers



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Pressure equipment – Directive 97/23/EC Conformity assessment procedure

- I = Module A
- II = Module A1, D1, E1
- III = Modules B1 + D, B1 + F, B + E, B + C1, H
- IV = Modules B + D, B + F, G, H1
- Categories: see annex II in directive





Checklist New approach directives

II. EU directives for products covered by the new approach

II.3. Pressure equipment

II.3.5 Simple pressure vessels Directive 87/404/EEC

II.3.5.1 Requirements regarding safety

II.3.5.2 Requirements regarding conformity assessment

II.3.5.3 Harmonized standards



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Checklist New approach directives

II.3 Pressure equipment

= *simple pressure vessels manufactured in series*
= *any welded vessel subjected to an internal gauge pressure greater than 0,5 bar which is intended to contain air or nitrogen and which is not intended to be fired*

Vessels in respect of which the product of PS and V exceeds 50 bar/litre



Vessels in respect of which the product of PS and V is 50 bar/litre or less => sound engineering practice (see annex II, 1.)





Checklist New approach directives

II.3 Simple pressure vessels

Vessels in respect of which the product of PS and V exceeds 50 bar/litre => vessel or data plate must bear the EC mark provided for in Article 16, together with at least the following information:

- the maximum working pressure PS in bar*
- the maximum working temperature T_{max} in $^{\circ}C$*
- the minimum working temperature T_{min} in $^{\circ}C$*
- the capacity of the vessel V in l*
- the name or mark of the manufacturer*
- the type and serial or batch identification of the vessel*

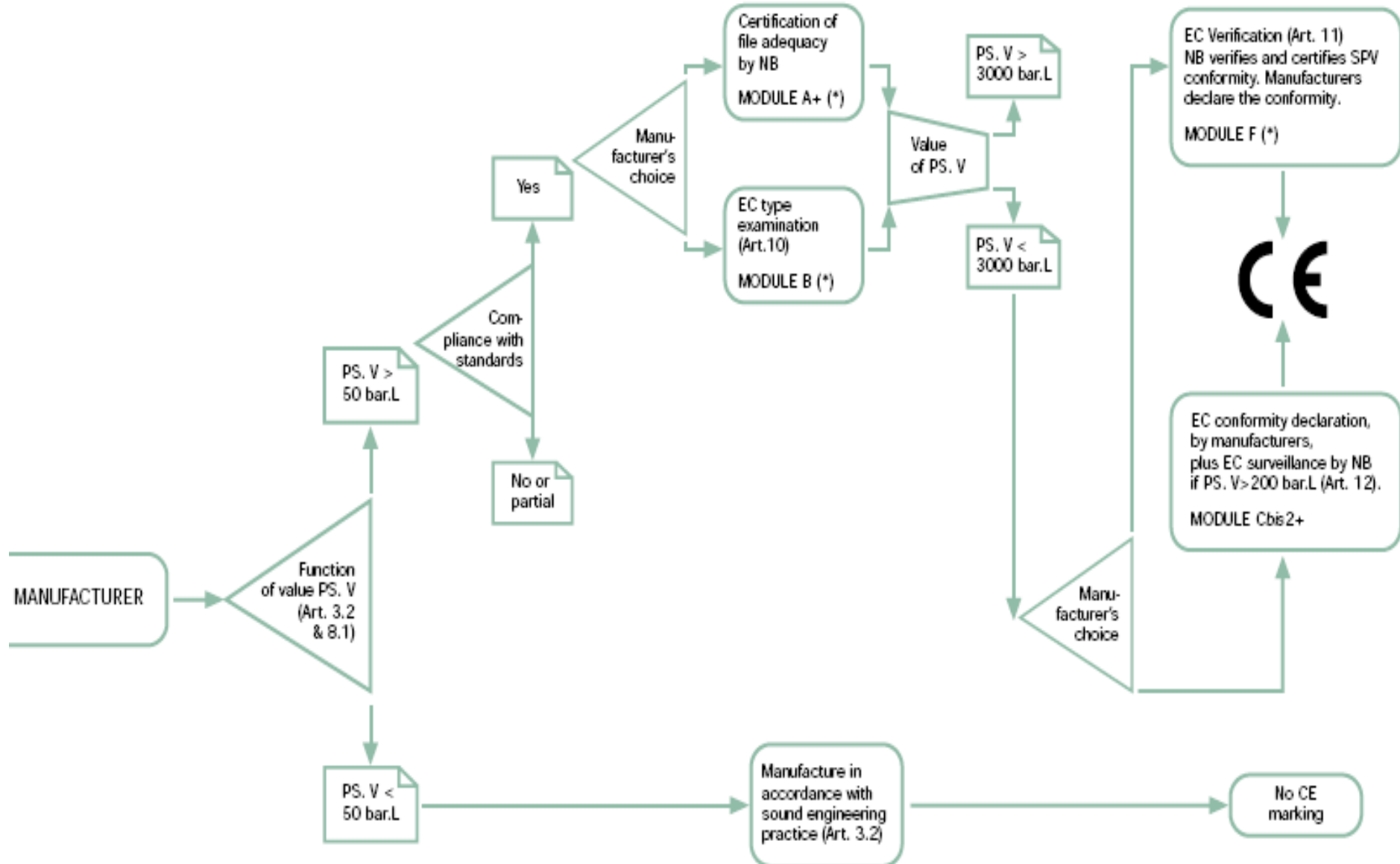
Annex I: essential safety requirements



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Simple pressure v. – Directive 87/404/EC Conformity assessment procedure





Checklist New approach directives

II. EU directives for products covered by the new approach

II.4. Medical devices

II.4.1 Medical devices: general Directive 93/42/EEC

II.4.1.1 Identification of the device

II.4.1.2 Requirements regarding safety

II.4.1.3 Requirements regarding conformity assessment

II.4.1.4 Harmonized standards



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Checklist New approach directives

II. 4 Medical devices

= any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- *diagnosis, prevention, monitoring, treatment or alleviation of disease*
- *diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap*
- *investigation, replacement or modification of the anatomy or of a physiological process*
- *control of conception*

And which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means



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Checklist New approach directives

II. 4 Medical devices

Annex I: essential requirements

Annex IX: product classes

Examples:

Class I: bands, elastic bands, elastic stocking, glasses, etc.

Class IIa: syringes, contact lenses, hearing aids, etc.

Class IIb: internal orthopaedic aids, solutions and liquids for contact lenses, medical appliances for high-frequency surgery, etc.

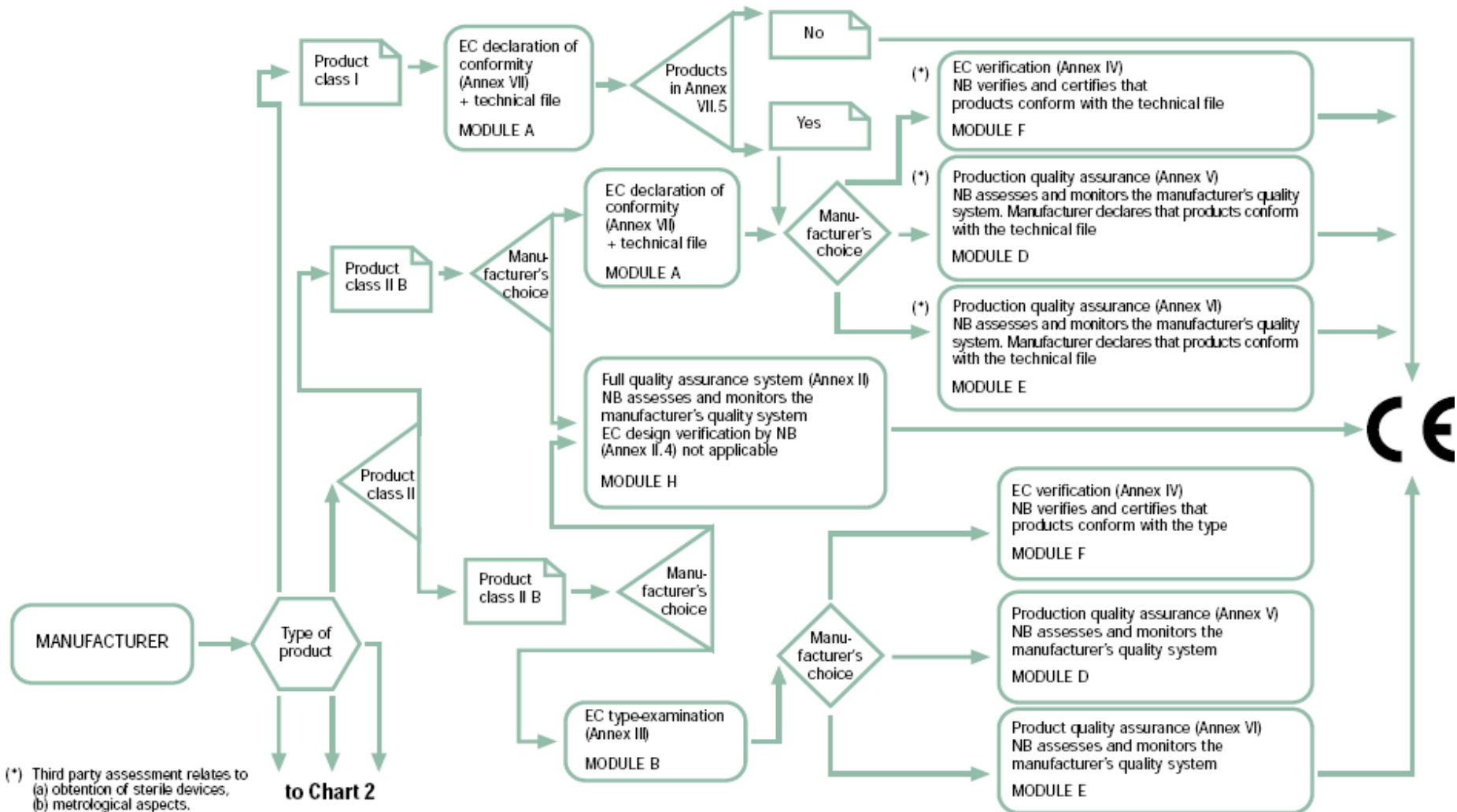
Class III: heart valves, absorbable surgical materials, etc.



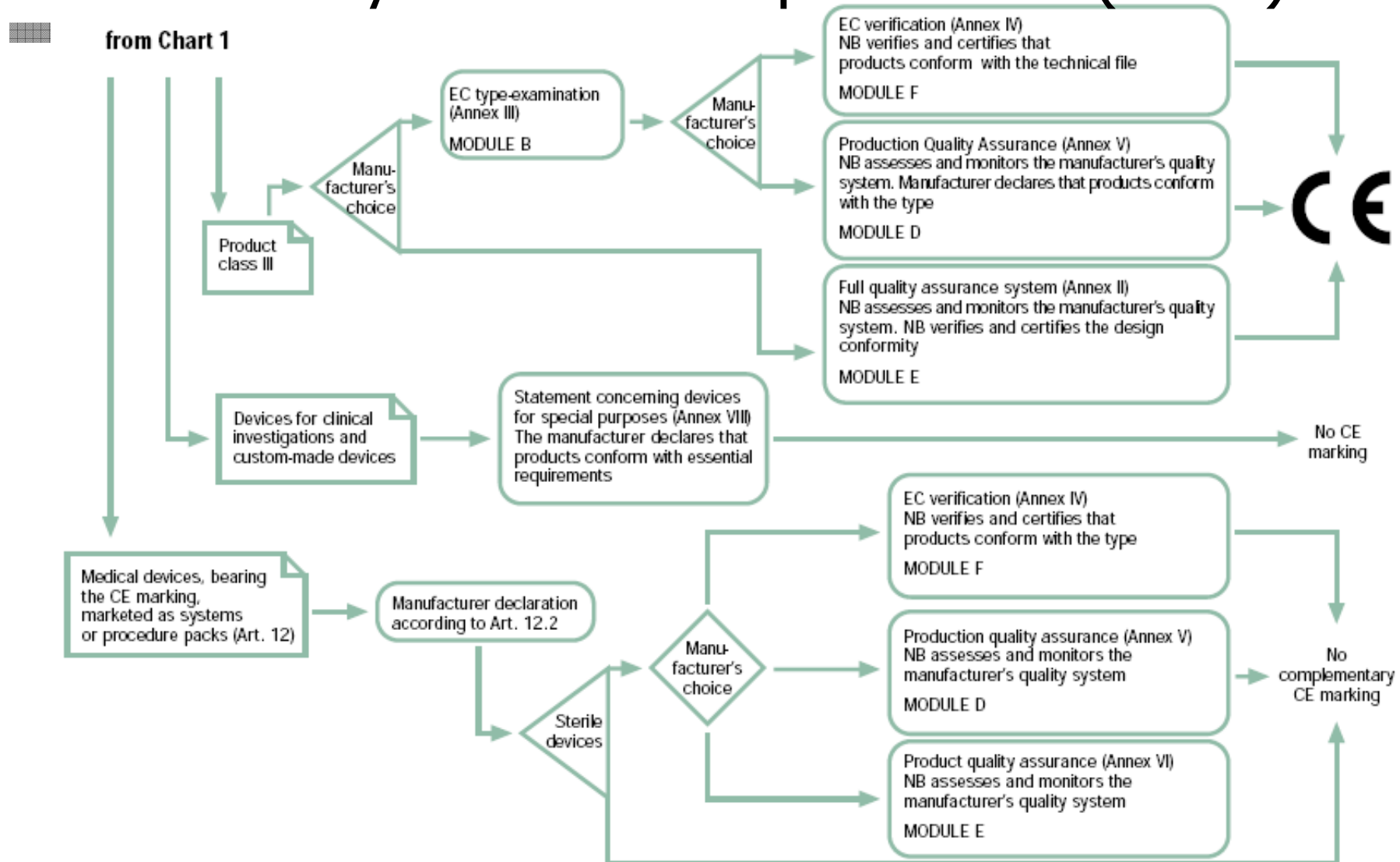
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Medical devices – Directive 93/42/EC

Conformity assessment procedure



Medical devices – Directive 93/42/EC Conformity assessment procedure (cont.)





Checklist New approach directives

II. EU directives for products covered by the new approach

II.4. Medical devices

II.4.2 In vitro diagnostic medical devices Directive 98/79/EEC

II.4.2.1 Identification of the device

II.4.2.2 Requirements regarding safety

II.4.2.3 Requirements regarding conformity assessment

II.4.2.4 Harmonized standards



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Checklist New approach directives

II.4 Medical devices – In vitro diagnostical devices

= any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

- concerning a physiological or pathological state, or*
- concerning a congenital abnormality, or*
- to determine the safety and compatibility with potential recipients, or*
- to monitor therapeutic measures*



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Checklist New approach directives

II.4 Medical devices – In vitro diagnostical devices

Examples:

implantable cardiac pacemakers, implantable nerve stimulators, bladder stimulators, etc.

Annex I: essential requirements

Annex II: List A and list B



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Checklist New approach directives

II.4 Medical devices

List A

- Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups: ABO system, rhesus (C, c, D, E, e) anti-Kell,
- reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of HIV infection (HIV 1 and 2), HTLV I and II, and hepatitis B, C and D.



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Checklist New approach directives

II.4 Medical devices

List B

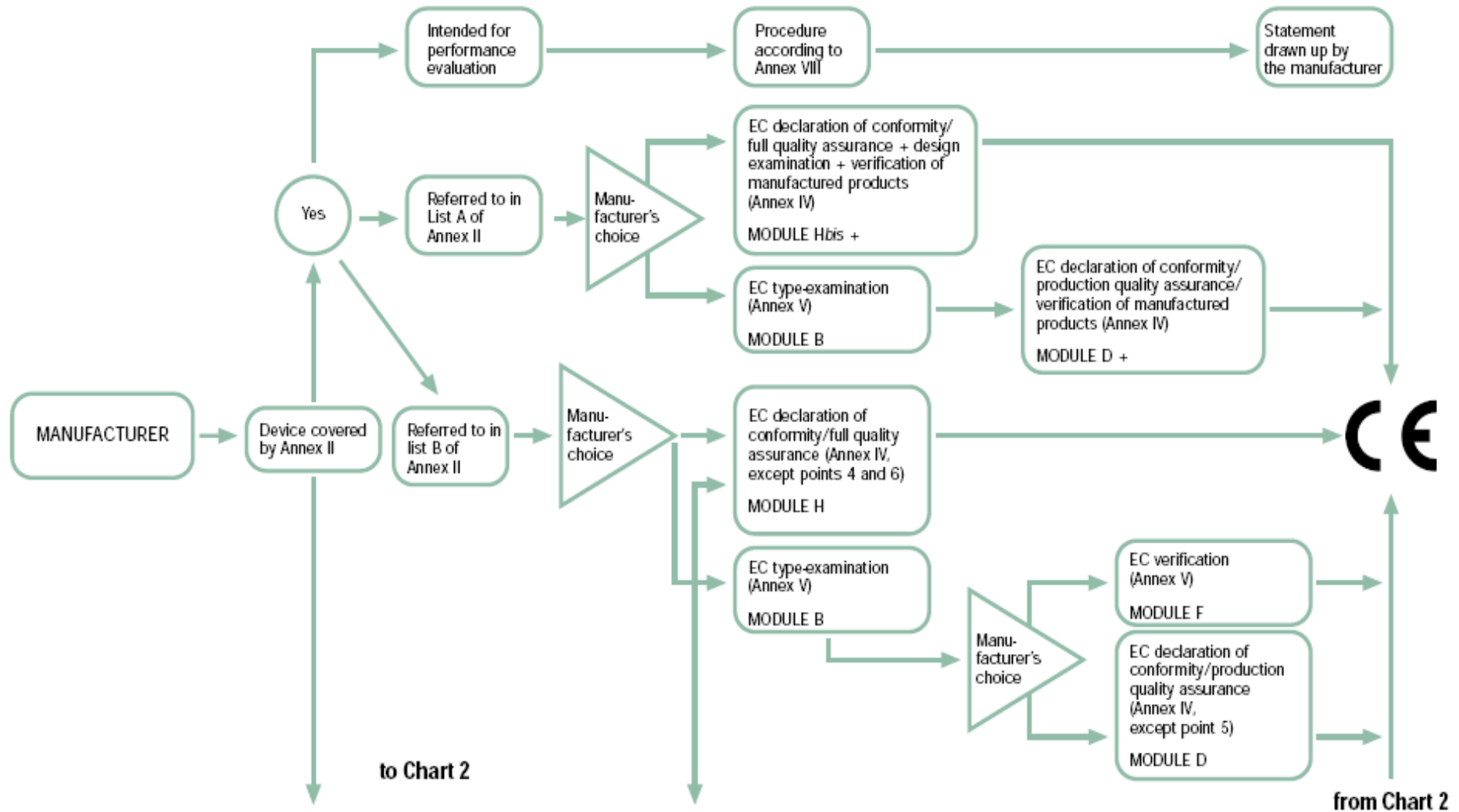
Includes products such as:

- Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups: anti-Duffy and anti-Kidd,
- reagents and reagent products, including related calibrators and control materials, for determining irregular anti-erythrocytic antibodies,
- reagents and reagent products, including related calibrators and control materials, for the detection and quantification in human samples of the following congenital infections: rubella, toxoplasmosis,
- ...

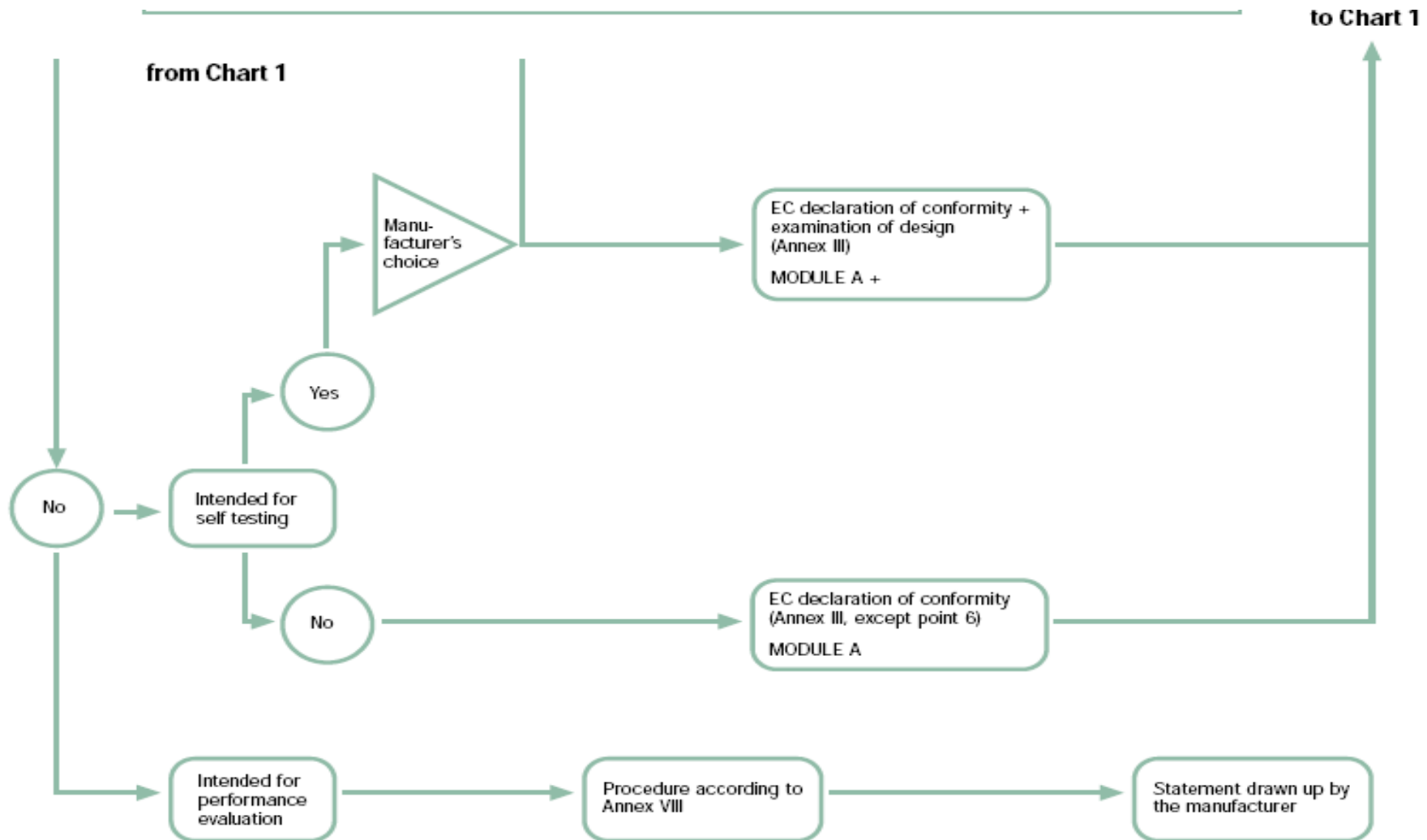


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In vitro diagnostic – Directive 98/79/EC Conformity assessment procedure



In vitro diagnostic m.d.– Dir. 98/79/EC Conformity assessment procedure (cont.)





Checklist New approach directives

II. EU directives for products covered by the new approach

II.4. Medical devices

II.4.3 Active implantable devices Directive 90/385/EEC

II.4.3.1 Identification of the device

II.4.3.2 Requirements regarding safety

II.4.3.3 Requirements regarding conformity assessment

II.4.3.4 Harmonized standards



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Checklist New approach directives

II.4 Medical devices – active implantable med. dev.

= any active medical device which is intended to be totally or partially introduced, surgically or medically into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure

Devices intended for clinical investigation or custom-made are covered by the Directive but cannot feature the CE marking!!!

(total definition, see art. 1)

Examples: phials, bottles, spatulas, glass plates, etc.



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Checklist New approach directives

II.4 Medical devices

Annex I: essential requirements

Article 9: types of products & procedure to follow

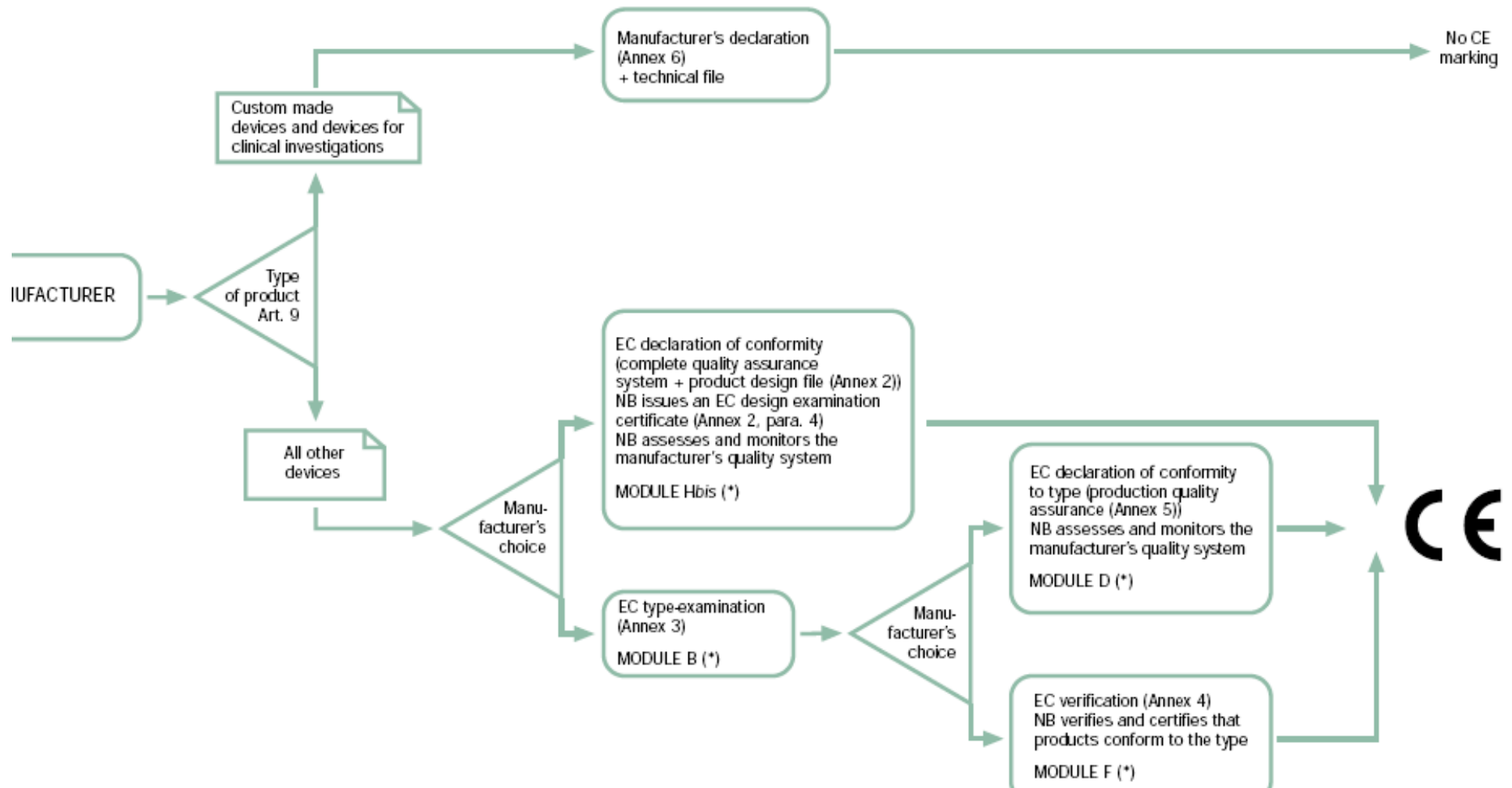
Annex VI: statement concerning devices intended for special purposes



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Active implantable m.d. – Dir. 90/385/EC Conformity assessment procedure





Checklist New approach directives

II. EU directives for products covered by the new approach

II.5. Electrical and electronic equipment and gas appliances

*II.5.1 Household appliances:
implementation of energy consumption labeling*

II.5.1.1 Identification - general

II.5.1.2 Identification - specific categories



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Checklist New approach directives

II. EU directives for products covered by the new approach

II.5. Electrical and electronic equipment and gas appliances

II.5.2 Requirements regarding energy labelling

II.5.2.1 Refrigerators, freezers and their combinations

II.5.2.2 Washing machines, dryers and their combination

II.5.2.3 Dishwashers

II.5.2.4 Ovens

II.5.2.5 Lighting sources

II.5.2.6 Air-conditioning appliances



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Checklist New approach directives

II. EU directives for products covered by the new approach

II.5. Electrical and electronic equipment and gas appliances

II.5.3 Domestic refrigeration appliances

II.5.3.1 Energy efficiency requirements

II.5.3.2 Technical documentation



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Checklist New approach directives

II.5. Electrical and electronic equipment and gas appliances – domestic refrigeration appliances

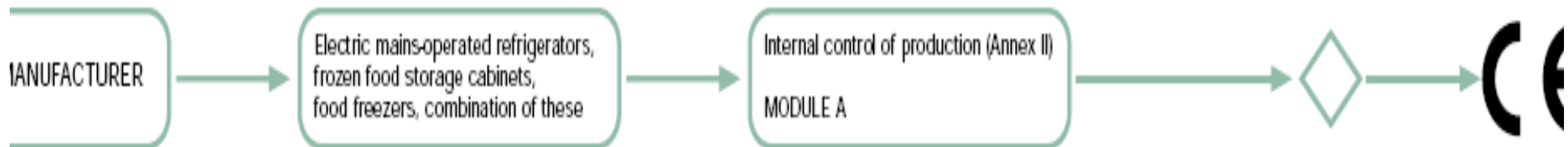
= electric mains-operated refrigerators, frozen food storage cabinets, food freezers, combination of these

Excluded are:

appliances which can also use other energy sources, particularly accumulators, and household refrigeration appliances working on the absorption principle and appliances manufactured on a one-off basis



Refrigeration appliances – Dir. 96/57/EC Conformity assessment procedure



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Checklist New approach directives

II. EU directives for products covered by the new approach

II.5. Electrical and electronic equipment and gas appliances

II.5.4 New hot-water boilers (energy efficiency) Directive 92/42/EEC

II.5.4.1 Identification

II.5.4.2 Efficiency and labeling requirements

II.5.4.3 Requirements regarding conformity assessment

II.5.4.4 Harmonized standards



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Checklist New approach directives

II.5. Electrical and electronic equipment and gas appliances - new hot-water boilers

= efficiency requirements applicable to new hot-water boilers fired by liquid or gaseous fuels with a rated output of no less than 4 kW and no more than 400 kW

=> check whether gas-fired or liquid-fired?

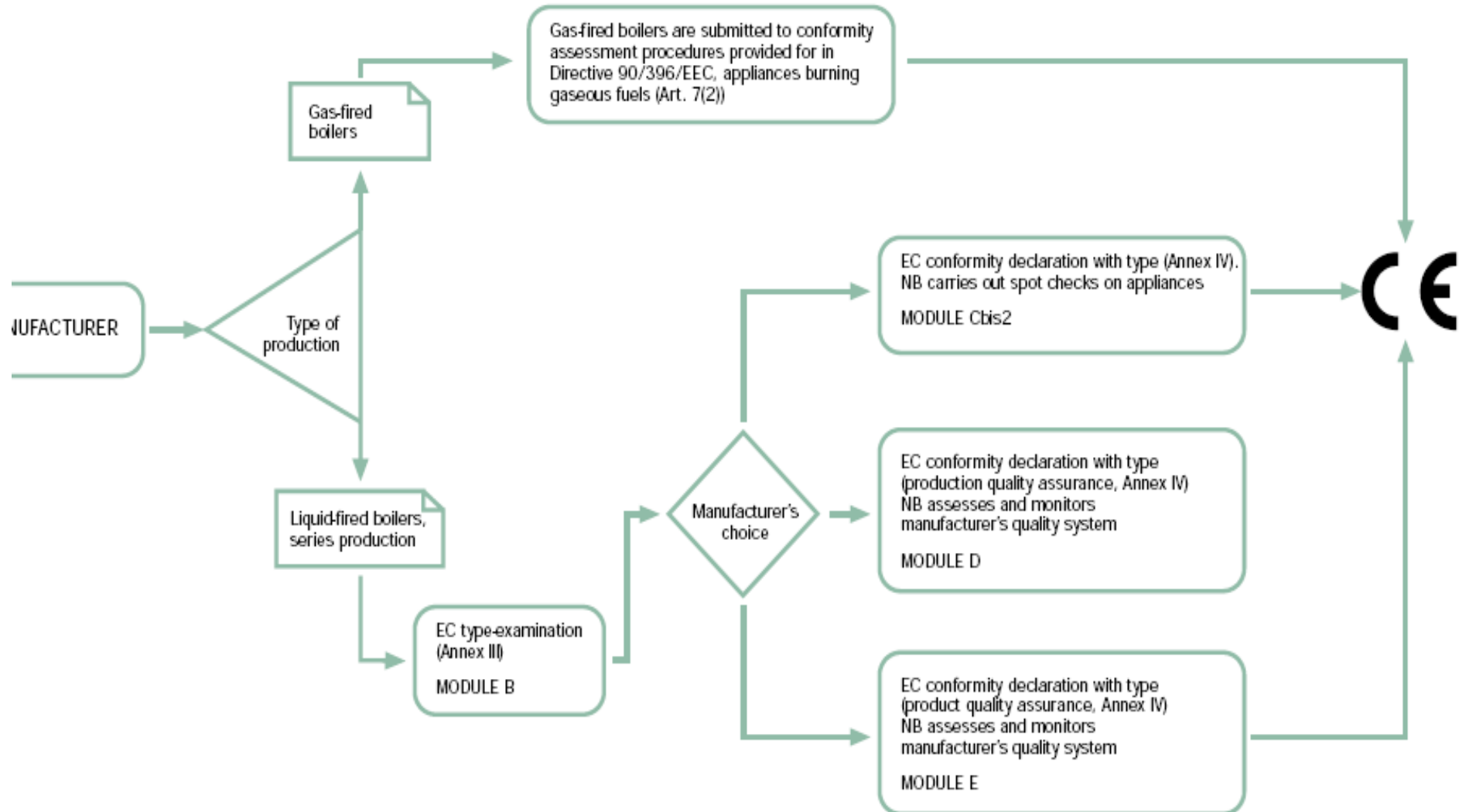
=> Directive 90/336/EEC applicable?

Exclusions (see article 3) are products such as:

boilers manufactured on a one-off basis, equipment for the instantaneous preparation of hot water, ...



New hot water boilers – Dir. 92/42/EC Conformity assessment procedure





Checklist New approach directives

II. EU directives for products covered by the new approach

II.5. Electrical and electronic equipment and gas appliances

II.5.5 Gas appliances Directive 90/396/EEC

II.5.5.1 Identification

II.5.5.2 Requirements regarding safety

II.5.5.3 Requirements regarding conformity assessment

II.5.5.4 Harmonized standards



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Checklist New approach directives

II.5 ... & gas appliances

Appliances

= burning gaseous fuels used for cooking, heating, hot water production, refrigeration, lighting or washing and having, where applicable, a normal water temperature not exceeding 105 °C

Equipment

= **safety devices**, controlling devices or regulating devices and sub-assemblies, other than forced draught burners and heating bodies to be equipped with such burners separately marketed for trade use and designed to be incorporated into an appliance burning gaseous fuel or assembled to constitute such an appliance

Gaseous fuel

= any fuel which is in a gaseous state at a temperature of 15°C under a pressure of 1 bar





Checklist New approach directives

II.5 ... & gas appliances

Art. 8:

In the case of production of an appliance as a single unit or in small quantities, EC verification by single unit may be chosen by the manufacturer

= simple design PPE

Annex I: essential requirements

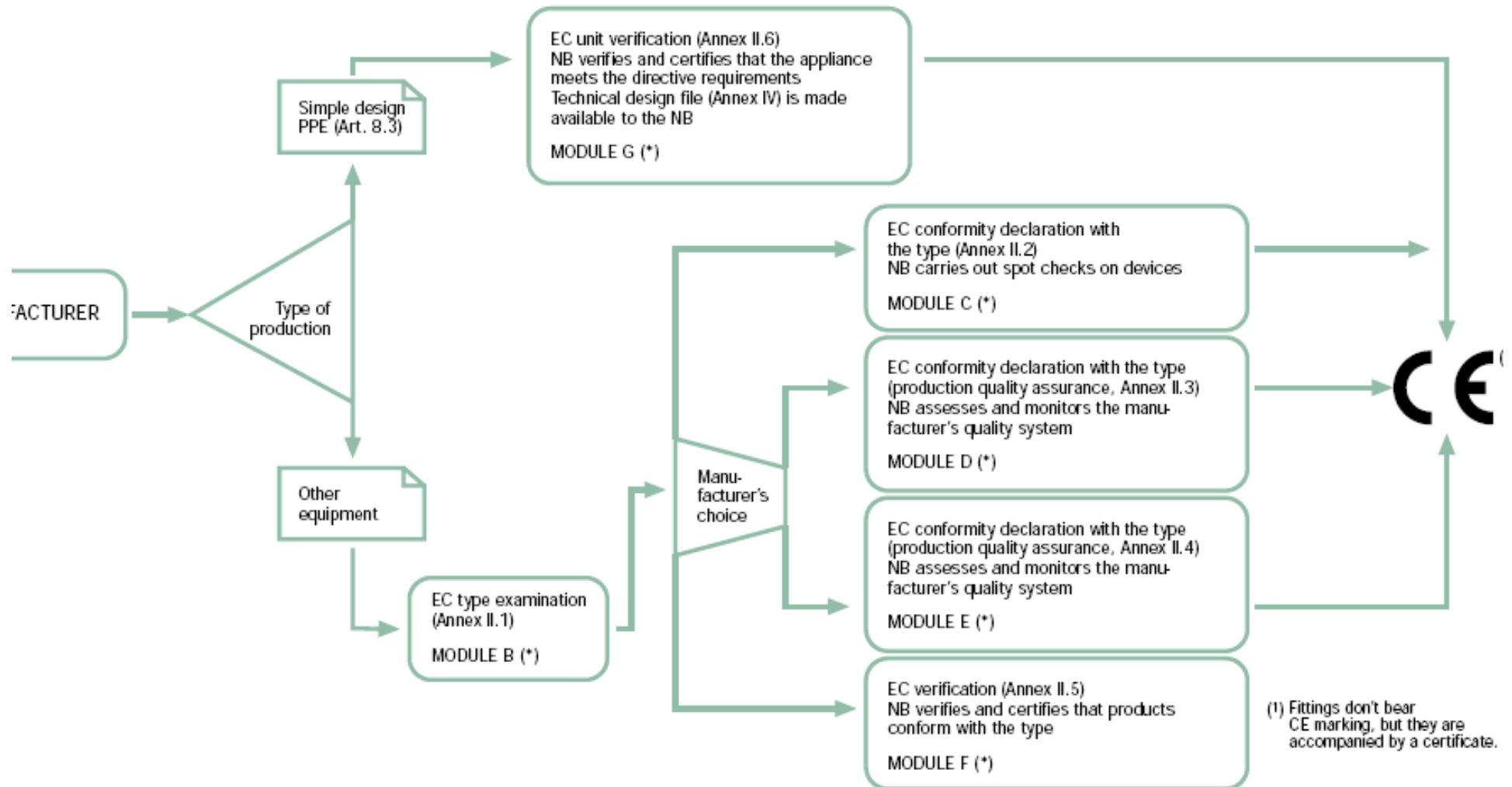
Excluded products are:

- *Appliances specifically designed for use in industrial processes carried out on industrial premises are excluded from this directive's application*



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Gas appliances – Dir. 90/396/EC Conformity assessment procedure





Checklist New approach directives

II. EU directives for products covered by the new approach

II.5. Electrical and electronic equipment and gas appliances

II.5.6 Ballasts for fluorescent lighting

II.5.6.1 Identification

II.5.6.2 Conformity with energy efficiency requirements

II.5.6.3 Harmonized standards



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Checklist New approach directives

II. EU directives for products covered by the new approach

II.5. Electrical and electronic equipment and gas appliances

II.5.7 Low-voltage electrical equipment Directive 73/23/EEC

II.5.7.1 Identification

II.5.7.2 Requirements regarding safety

II.5.7.3 Requirement regarding conformity assessment

II.5.7.4 Harmonized standards



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Checklist New approach directives

II.5 Electrical and electronic equipment and gas appliances – low voltage electr. equipment

= any equipment designed for use with a voltage rating of between 50 and 1000 V for alternating current and between 75 and 1500 V for direct current, other than the equipment and phenomena listed in annex II.

Examples:

- electrical domestic appliances, tools, cables, leading wires, machinery carrying primarily electrical risks, ...

Excluded are products such as:

- specialized electrical equipment, for use on ships, aircraft or railways, electr. eq. for use in explosive atmosphere, for radiology and medical purposes, electricity meters, ...



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Checklist New approach directives

II.5 Electrical and electronic equipment and gas appliances – low voltage electr. equipment

Annex I: essential requirements of safety

1. General conditions
2. Protection against hazards arising from the electrical equipment
3. Protection against hazards which may be caused by external influences on the electrical equipment

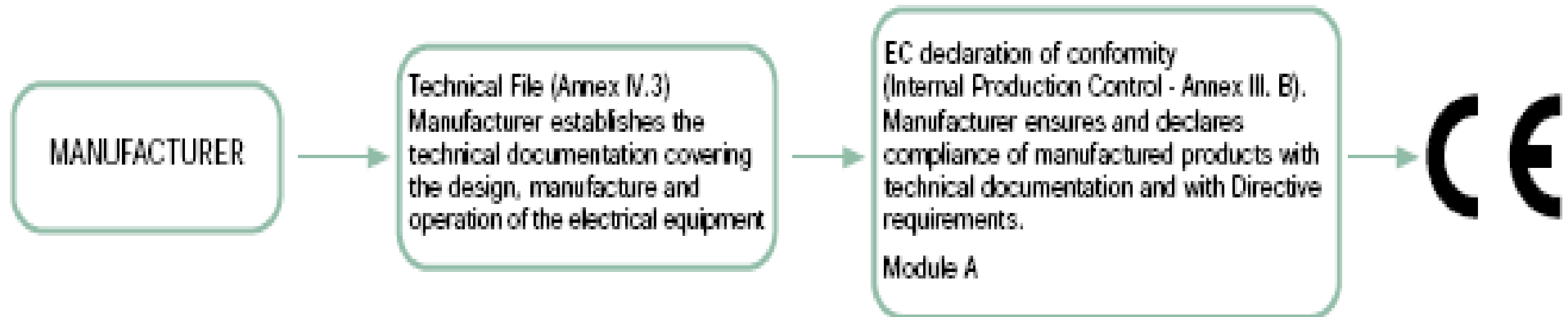
Annex II: equipment and phenomena outside the scope of this Directive



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Low voltage electrical equipment – Directive 73/23/EEC Conformity assessment procedure



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Checklist New approach directives

II. EU directives for products covered by the new approach

II.5. Electrical and electronic equipment and gas appliances

II.5.8 Electromagnetic compatibility of electrical and electronic apparatus Directive 89/336/EEC

II.5.8.1 Identification

II.5.8.2 Requirements regarding electromagnetic disturbance

II.5.8.3 Requirements regarding conformity assessment

II.5.8.4 Harmonized standards

II.5.8.5 Requirements regarding product information (only applying to apparatus)



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Checklist New approach directives

II.5 Electromagnetic compatibility

= the ability of equipment to function satisfactorily in its electromagnetic environment without introducing intolerable electromagnetic disturbances to other equipment in that environment

Examples:

mobile telephones, computers, hi-fi stereo, electrical household appliances, navigation tools, ...

Excluded are products such as:

components such as fuses, integrated circuits, resistances, ...

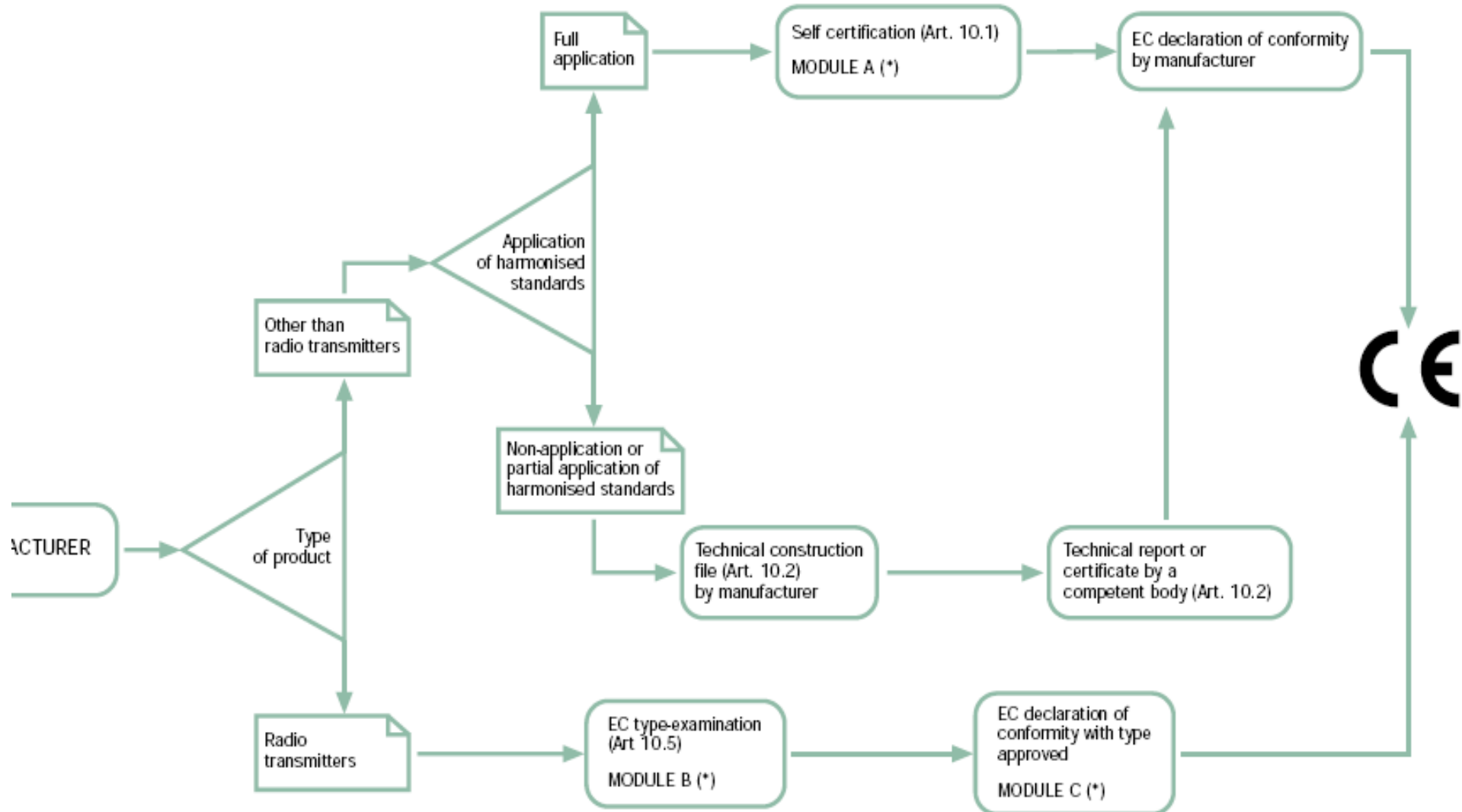
Annex III: essential safety requirements



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Electromagnetic compatibility – Directive 2004/108/EC Conformity assessment procedure





Checklist New approach directives

II. EU directives for products covered by the new approach

II.6. Radio and telecommunications terminal equipment

Directive 99/5/EC

II.6.1 Identification

II.6.2 Requirements regarding safety and harmonized European standards

II.6.3 Information and notification requirements

II.6.4 Requirements regarding conformity assessment

II.6.5 Harmonized standards



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Checklist New approach directives

II.6 Radio and telecommunications terminal equipment

telecommunications terminal equipment

= a product enabling communication or a relevant component thereof which is intended to be connected directly or indirectly by any means whatsoever to interfaces of public telecommunications networks (that is to say, telecommunications networks used wholly or partly for the provision of publicly available telecommunications services)

radio equipment

= a product, or relevant component thereof, capable of communication by means of the emission and/or reception of radio waves utilising the spectrum allocated to terrestrial/space radiocommunication



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Checklist New approach directives

II.6 Radio and telecommunications terminal equipment

Art. 3: essential requirements

1. general

2. in addition, requirements regarding radio equipment

R.E. shall be so constructed that it effectively uses the spectrum allocated to terrestrial/space radio communication and orbital resources so as to avoid harmful interference

Annex I: equipment not covered by the directive

Examples of exclusions:

radio equipment used by radio amateurs unless the equipment is available commercially, marine equipment, cabling and wiring, receive only radio equipment intended to be used solely for the reception of sound and TV broadcasting services, ...



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Checklist New approach directives

II. EU directives for products covered by the new approach

II.7 Recreational craft Directive 94/25/EC

II.7.1 Identification

*II.7.2 Rules on different kinds of emissions directive
applying to recreational craft*

II.7.2.1 Rules on exhaust emissions

II.7.2.2 Rules on noise emissions

II.7.3 Requirements regarding safety

II.7.4 Requirements regarding conformity assessment

II.7.5 Harmonized standards



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Checklist New approach directives

II.7 Recreational craft

= any boat of any type, regardless of the means of propulsion, from 2,5 to 24 m hull length, measured according to the appropriate harmonized standards intended for sports and leisure purposes

Also applies:

partly completed boats and components when separate and when installed.

!!! The fact that the same boat could be used for charter or for recreational boating training shall not prevent it being covered by this Directive when it is placed on the market for recreational purposes.



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Checklist New approach directives

II.7 Recreational craft

Examples of products:

boats, ignition-protected equipment for inboard and stern drive engines, steering wheels, fuel tanks and fuel hoses: prefabricated hatches and portlights

Excluded are products such as (see art. 1.3)

craft intended solely for racing, canoes and kayaks, gondolas and pedalos, sailing surfboards, craft specifically intended to be crewed and to carry passengers for commercial purposes, ...



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Checklist New approach directives

II.7 Recreational craft

Annex I: categories of recreational craft

- A. OCEAN
- B. OFFSHORE
- C. INSHORE
- D. SHELTERED WATERS

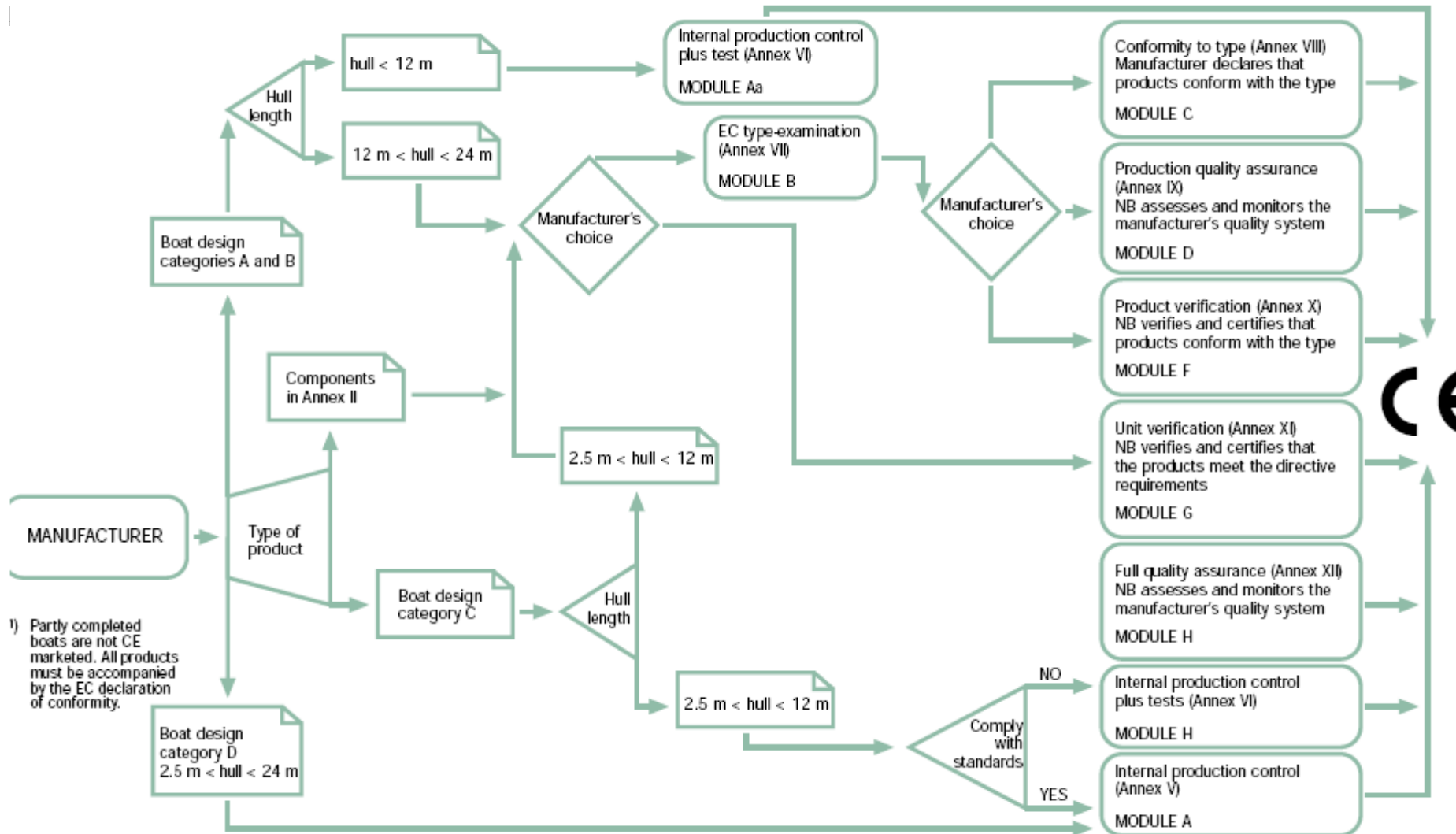
Annex II: categories of components

Annex I: essential safety requirements for the design and construction of recreational craft



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Recreational craft – Dir. 94/25/EC Conformity assessment procedure





Checklist New approach directives

II. EU directives for products covered by the new approach

II.8 Metrology

II.8.1 Non-automatic weighing instruments Directive 90/384/EEC

II.8.1.1 Identification

II.8.1.2 Requirements regarding safety

*II.8.1.3 Requirements regarding conformity
assessment*

II.8.1.4 Technical documentation and marking

II.8.1.5 Harmonized standards



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Checklist New approach directives

II. EU directives for products covered by the new approach

II.8 Metrology

II.8.2 Measuring instruments

II.8.2.1 Identification

II.8.2.2 Requirements regarding level of confidence

II.8.2.3 Requirements regarding conformity assessment

II.8.2.4 Technical documentation

II.8.2.5 Harmonized standards



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Checklist New approach directives

II.8 Metrology

Non-automatic weighing instruments

A weighing instrument is defined as a measuring instrument serving to determine the mass of a body by using the action of gravity on that body. A weighing instrument may also serve to determine other mass-related magnitudes, quantities, parameters or characteristics.

A non-automatic weighing instrument is defined as a weighing instrument requiring the intervention of an operator during weighing.

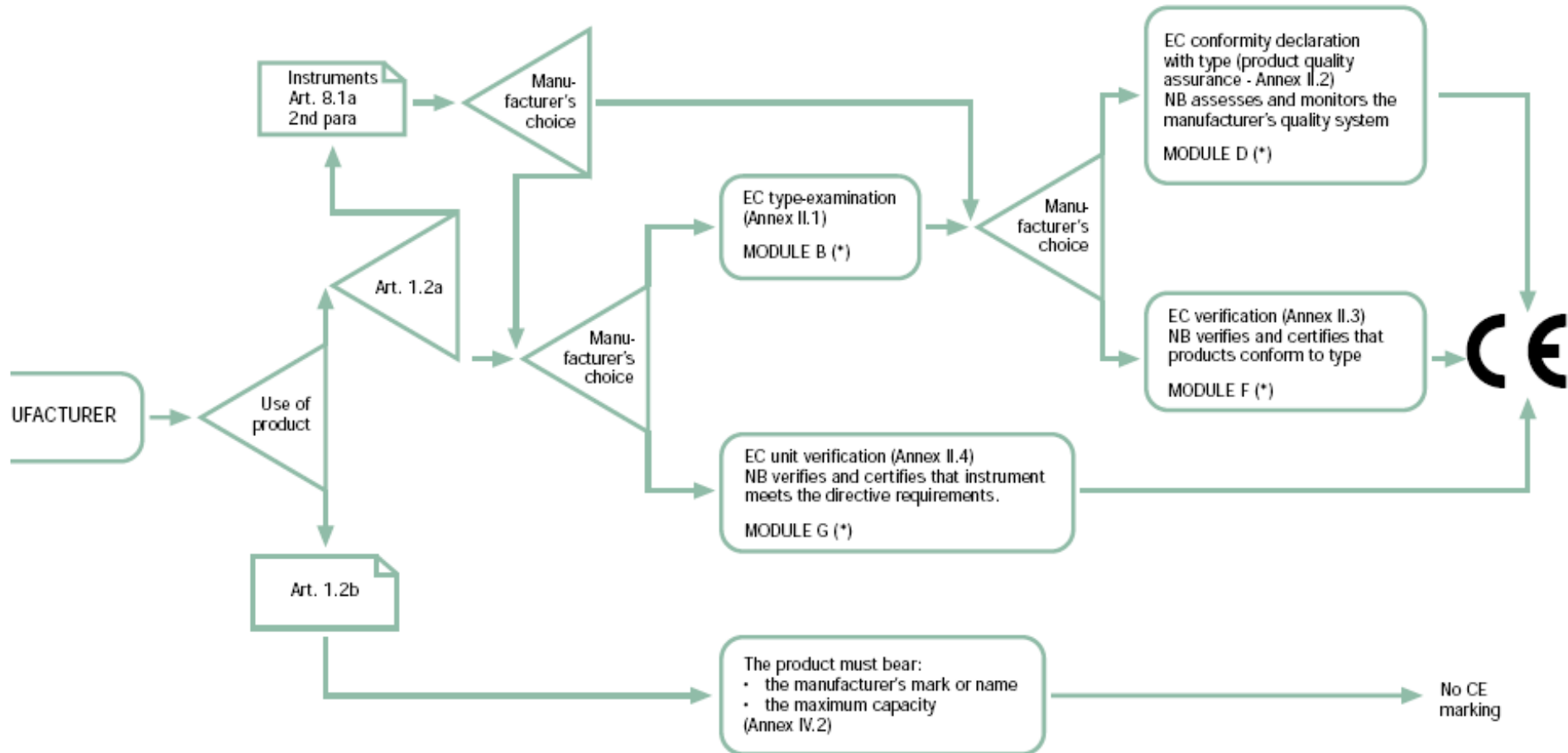
- Two kinds of use (categories) (see art. 1):
 - Measure of mass in all kinds of applications
 - Other applications



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Non-automatic weighing instruments – Directive 90/384/EC Conformity assessment procedure





Checklist New approach directives

II. EU directives for products covered by the new approach

II.9 Explosives intended for civilian use

Directive 93/15/EC

- II.9.1 Identification*
- II.9.2 Requirements regarding safety*
- II.9.3 Requirements regarding conformity assessment*
- II.9.4 Supervision of transfers of explosives*
- II.9.5 Harmonized standards*



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Checklist New approach directives

II.9 Explosives intended for civilian use

= the materials and articles considered to be such in the United Nations recommendations on the transport of dangerous goods and falling within Class 1 of those recommendations

Excluded are products such as:

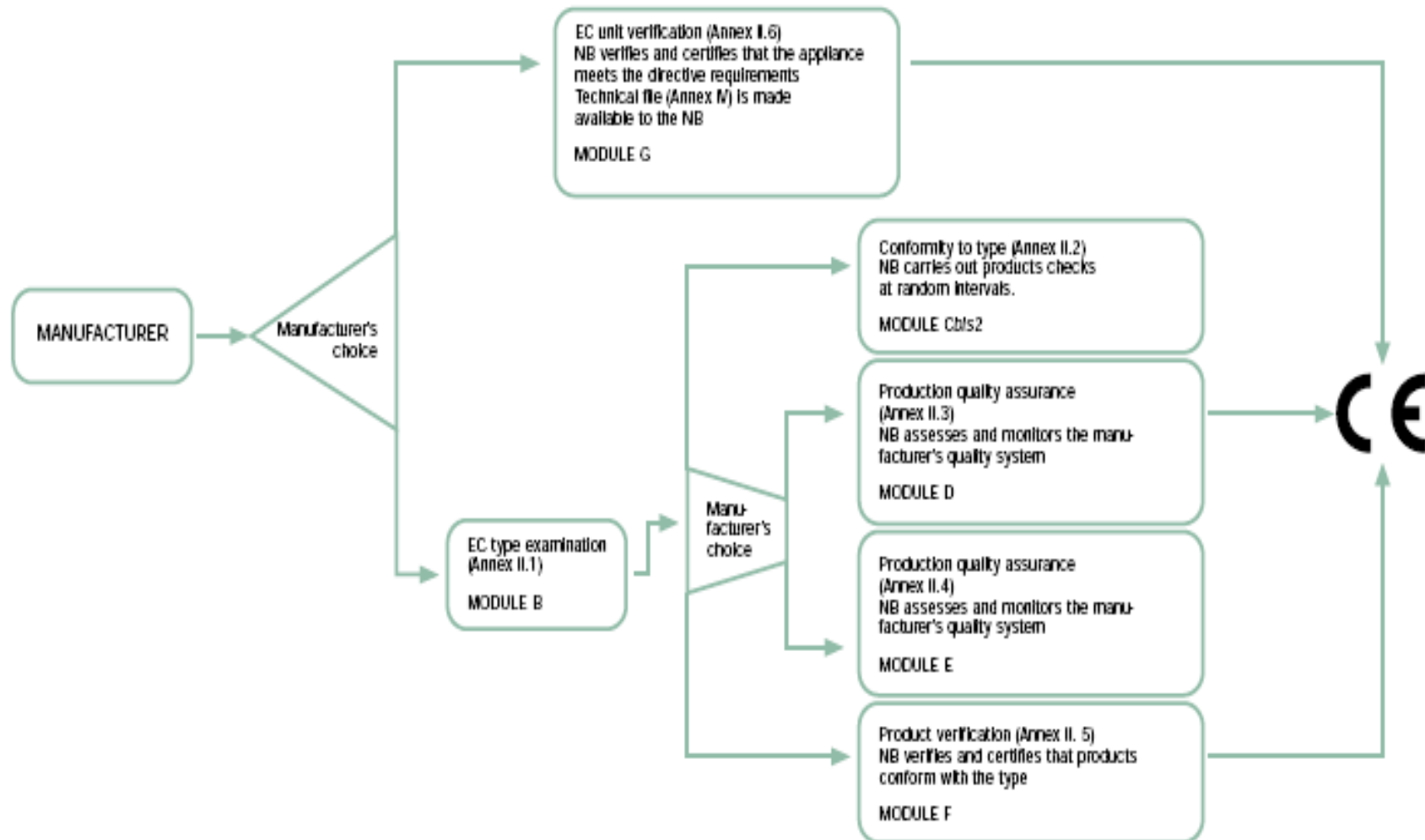
explosives, including ammunition, intended for use, in accordance with national law, by the armed forces or the police, pyrotechnical articles, ammunition, except as provided in Articles 10, 11, 12, 13, 17, 18 and 19

Annex I: essential safety requirements



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Explosives for civil uses - Directive 93/15/EC Conformity assessment procedure





Checklist New approach directives

II. EU directives for products covered by the new approach

II.10 Materials used outdoors

Directive 2000/14/EC

II.10.1 Identification of the material used outdoors

II.10.2 Rules on environmental noise management

II.10.3 Requirements regarding conformity assessment

II.10.4 Harmonized standards



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Checklist New approach directives

II.10 Materials used outdoors

Examples:

aerial access platform with combustion engines, brush cutter, building site hoist, lawnmower, motor compressor,

Annex II: essential requirements

*Art. 12: products following simple procedure
(only module A required)*

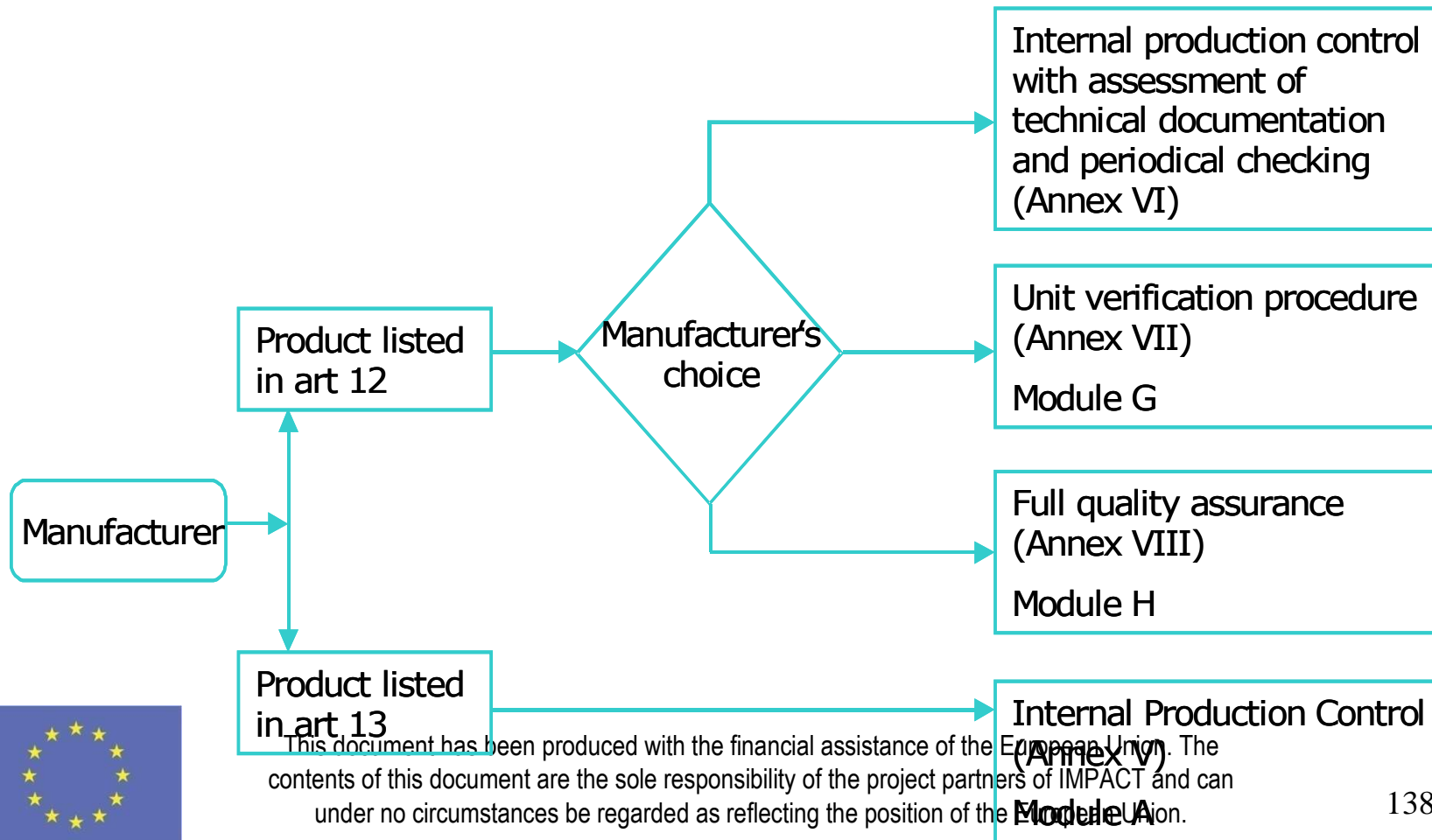
Art. 13: products following other procedure



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Materials used outdoors - Directive 2000/14/EC

Conformity assessment procedure



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Checklist New approach directives

II. EU directives for products covered by the new approach

II.11 Construction products

Directive 89/106/EC

II.11.1 Identification

II.11.2 Requirements regarding safety

II.11.3 Requirements regarding conformity assessment

II.11.4 Harmonized standards



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Checklist New approach directives

II.11 Construction products

= products which is produced with a view to their incorporation in a **permanent manner** in construction works, including both buildings and civil engineering works

Examples:

glues, putty, pipe filling, fittings, metal anchors, plaster, chimney and chimney bricks, stairs, doors, windows, solar power units, heat insulating materials, ...



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Checklist New approach directives

II.11 Construction products

Annex I: essential requirements

- Mechanical strength and stability
- Safety in the event of fire
- Hygiene, health and the environment
- Safety in use
- Protection against noise
- Energy economy and heat retention



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Checklist New approach directives

II.11 Construction products

- *Attestation of conformity depending on:*
 - factory production control system?
 - certain cases: certification body necessary
 - Batch production vs. individual production



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Construction products - Directive 89/106/EC Conformity assessment procedure

(i) Certification of the conformity of the product by an approved certification body

OR:

(ii) Declaration of conformity of the product by the manufacturer



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II.11 Construction products

(i) Certification of the conformity of the product by an approved certification body

- (1) factory production control;
- (2) further testing of samples taken at the factory by the manufacturer in accordance with a prescribed test plan;

- (3) initial type-testing of the product;
- (4) initial inspection of factory and of factory production control;
- (5) continuous surveillance, assessment and approval of factory production control;
- (6) possibly, audit-testing of samples taken at the factory, on the market or on the construction site.



II.11 Construction products

(ii) Declaration of conformity of the product by the manufacturer

First possibility:

- (1) initial type-testing of the product;
- (2) factory production control;
- (3) possibly, testing of samples taken at the factory in accordance with a prescribed test plan;

- (4) certification of factory production control on the basis of:
 - initial inspection of factory and of factory production control,
 - possibly, continuous surveillance, assessment and approval of factory production control.





(ii) Declaration of conformity of the product by the manufacturer

Second possibility:

- (1) initial type-testing of the product by an approved laboratory;
- (2) factory production control

Third possibility:

- (a) initial type-testing by the manufacturer;
- (b) factory production control



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Checklist New approach directives

II. EU directives for products covered by the new approach

II.12 Personal protective equipment

Directive 89/686/EC

II.12.1 Identification

II.12.2 Requirements regarding safety

II.12.3 Requirements regarding conformity assessment

II.12.4 Harmonized standards



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Checklist New approach directives

II.12 Personal protective equipment

= any device or appliance designed to be worn or held by an individual for protection against one or more health and safety hazards

Examples:

protective goggles, waistcoat to provide protection, helmets, forearm protectors, lower-leg protector, breathing masks, ...



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Checklist New approach directives

II.12 Personal protective equipment

Types of product:

Art. 8.3:

EC type-examination not required for simple design PPE

Art. 8.4 a:

Among others:

- *filtering respiratory devices for protection against solid and liquid aerosols or irritant, dangerous, toxic or radiotoxic gases,*
- *respiratory protection devices providing full insulation from the atmosphere, including those for use in diving,*
- *PPE to protect against falls from a height,*
- *motor cycle helmets and visors*
- ...



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Checklist New approach directives

II.12 Personal protective equipment

Annex I: exclusions from the directive

Excluded are products such as:

- PPE designed and manufactured specifically for use by the armed forces or in the maintenance of law and order (cfr helmets, ...)
- PPE for self-defence (personal deterrent weapons, ...)

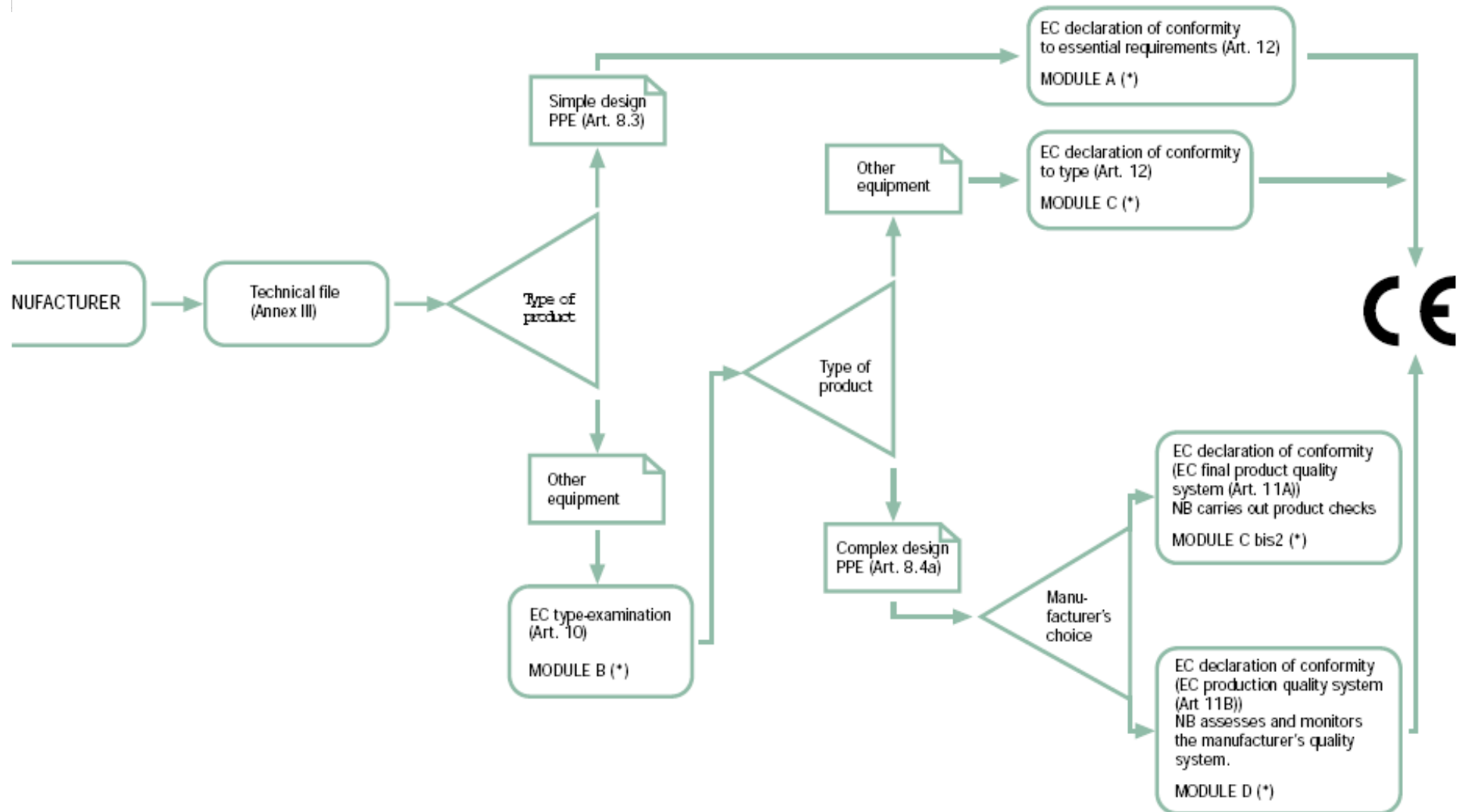
Annex II: basic health and safety requirements

- *General*
- *Additional applicable to several classes of PPE*
- *Specific to particular risks*





Personal protective equipment (PPE) – Directive 89/686/EC Conformity assessment procedure





Checklist New approach directives

II. EU directives for products covered by the new approach

II.13 Equipment and protective systems intended for use in potentially explosive atmospheres

Directive 94/9/EC

II.13.1 Identification

II.13.2 Requirements regarding safety

II.13.3 Requirements regarding conformity assessment

II.13.4 Harmonized standards



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Checklist New approach directives

II.13 Equipment and protective systems intended for use in potentially explosive atmospheres

= Equipment and protective systems intended to be used in a potentially explosive atmosphere. Safety devices, controlling devices and regulating devices intended for use outside potentially explosive atmospheres but required for or contribuant to the safe functioning of equipment and protective systems with respect to the risks of explosion are also covered by this Directive



Checklist New approach directives

II.13 Equipment and protective systems intended for use in potentially explosive atmospheres

Types of products (see annex I):

- Art. 8.1 (a) and 8.2:** *equipment-group I and II, equipment-category M 1 & 1 (very high level of protection)*
- Art. 8.1 (b):** *equipment-group I and II, equipment-category M 2 & 2 (high level of protection)*
- Art. 8.1 (c):** *equipment-group II, equipment-category 3 (normal level of protection)*

Annex II: essential safety requirements

- *Common requirements*
- *Supplementary requirements in respect of equipment*
- *Supplementary requirements in respect of protective systems*

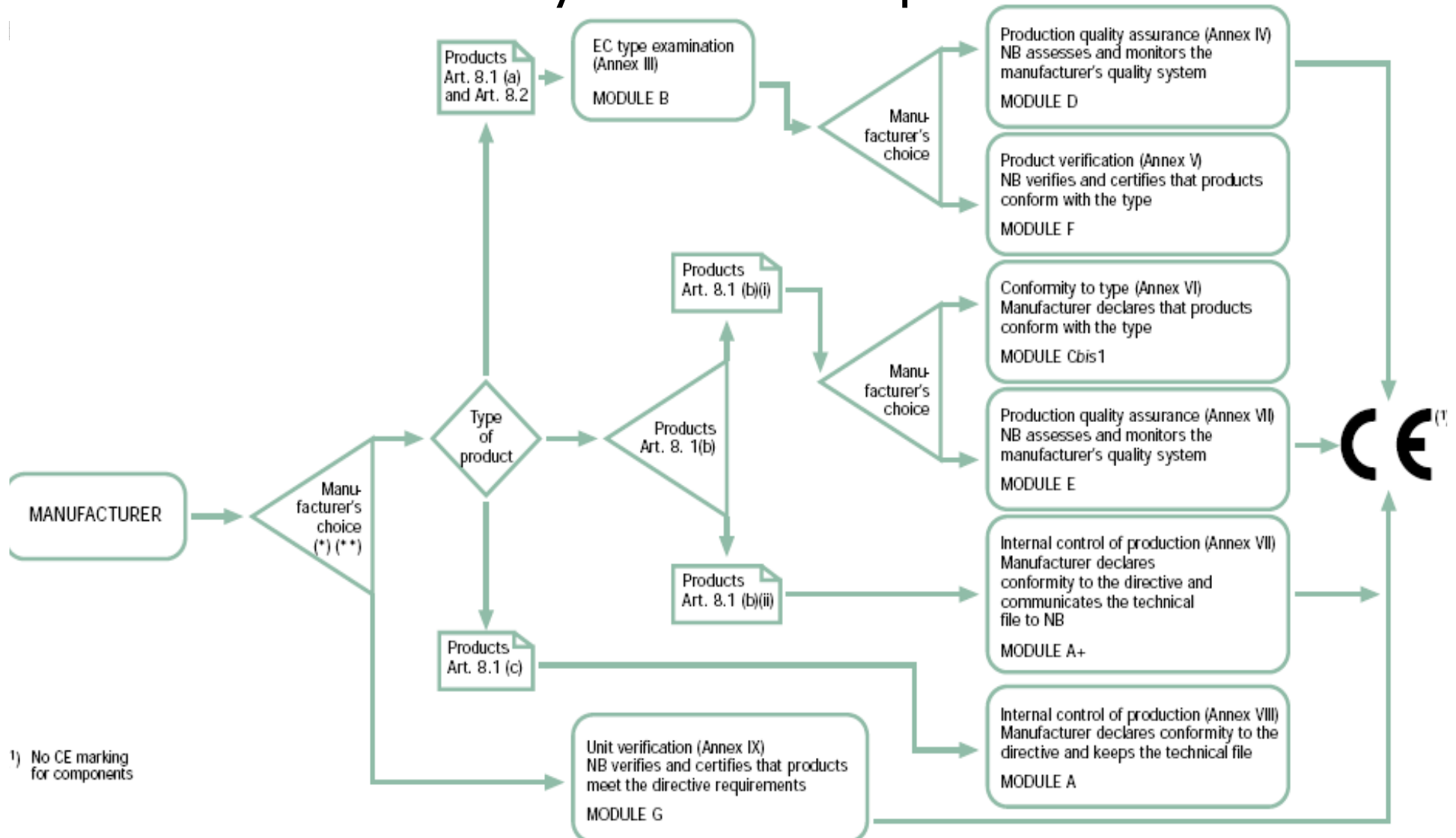


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...intended for use in potential explosive atmospheres – Directive 94/9/EC

Conformity assessment procedure



1) No CE marking for components



Checklist New approach directives

3. Overview different directives: general background for auditing

Questions?



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Thank you for your attention!

Further requests or information?

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